

closed to the public since all portions of the meetings will concern matters that are exempted from disclosure under the provisions of section 552(b)(3), (4), (6) and (7) of Title 5 of the U.S. Code. This determination, which is in accordance with section 10(d) of the Federal Advisory Committee Act, is necessary to protect the confidentiality of tax returns and return information as required by section 6103 of the Internal Revenue Code.

Statement of Public Interest. It is in the public interest to continue the existence of the Art Advisory Panel. The Secretary of the Treasury, with the concurrence of the General Services Administration, has approved

reestablishment of the Panel. The membership of the Panel is balanced between museum directors and art dealers to afford differing points of view in determining fair market value.

Fifteen days after publication of this notice in the *Federal Register*, the Department of the Treasury, will file a copy of the committee's charter with the Senate Finance Committee and the Committee Ways and Means Committee of the U.S. House of Representatives. The Department of the Treasury will also furnish a copy of the charter to the Library of Congress and the General Services Administration.

Authority for this panel will expire two years from the date the charter is filed with the appropriate congressional

committees unless, prior to the expiration of its charter, the Panel is renewed.

The Assistant Secretary (Management) has determined that this document is not a major rule as defined in Executive Order 12291 and that a regulatory impact analysis therefore is not required. Neither does this document constitute a rule subject to the Regulatory Flexibility Act (5 U.S.C. chapter 6).

Dated: February 10, 1994.

George Muñoz,

Assistant Secretary (Management).

[FR Doc. 94-3467 Filed 2-14-94; 8:45 am]

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Sunshine Act Meetings

Federal Register

Vol. 59, No. 31

Tuesday, February 15, 1994

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

UNITED STATES POSTAL SERVICE BOARD OF GOVERNORS

Notice of Vote to Close Meeting

At its meeting on February 7, 1994, the Board of Governors of the United States Postal Service voted unanimously to close to public observation its meeting scheduled for March 7, 1994, in Washington, DC. The members will discuss preparations for the rate case filing.

The meeting is expected to be attended by the following persons: Governors Alvarado, Daniels, del Junco, Dyhrkopp, Mackie, Pace, Setrakian and Winters; Postmaster General Runyon, Deputy Postmaster General Coughlin, Secretary to the Board Harris, and General Counsel Elcano.

The Board determined that pursuant to section 552b(c)(3) of Title 5, United States Code, and section 7.3(c) of Title 39, Code of Federal Regulations, this portion of the meeting is exempt from the open meeting requirement of the Government in the Sunshine Act [5 U.S.C. 552b(b)] because it is likely to disclose information in connection with proceedings under Chapter 36 of Title 39, United States Code (having to do with postal ratemaking, mail classification and changes in postal services), which is specifically exempted from disclosure by section 410(c)(4) of Title 39, United States Code.

The Board has determined further that pursuant to section 552b(c)(10) of Title 5, United States Code, and section 7.3(j) of Title 39, Code of Federal Regulations, the discussion is exempt because it is likely to specifically concern participation of the Postal Service in a civil action or proceeding involving a determination on the record after opportunity for a hearing. The Board

further determined that the public interest does not require that the Board's discussion of the matter be open to the public.

In accordance with section 552b(f)(1) of Title 5, United States Code, and section 7.6(a) of title 39, Code of Federal Regulations, the General Counsel of the United States Postal Service has certified that in her opinion the meeting may properly be closed to public observation pursuant to section 552b(c)(3) and (10) of Title 5, United States Code; section 410(c)(4) of Title 39, United States Code; and section 7.3 (c) and (j) of Title 39, Code of Federal Regulations.

Requests for information about the meeting should be addressed to the Secretary of the Board, David F. Harris, at (202) 268-4800.

David F. Harris,

Secretary.

[FR Doc. 94-3567 Filed 2-10-94; 4:58 pm]

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Federal Register

Tuesday
February 15, 1994

Part II

**Department of
Transportation**

Federal Aviation Administration
Federal Highway Administration
Federal Railroad Administration
Federal Transit Administration
Research and Special Programs
Administration

Limitation on Alcohol Use by
Transportation Workers; Notice

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****Federal Highway Administration****Federal Railroad Administration****Federal Transit Administration****Research and Special Programs Administration**

RIN Nos. 2120-AE43; 2125-AC85; 2130-AA43; 2132-AA38; 2137-AC21.

Limitation on Alcohol Use by Transportation Workers

AGENCIES: The Federal Aviation Administration (FAA), the Federal Highway Administration (FHWA), the Federal Railroad Administration (FRA), the Federal Transit Administration (FTA) and the Research and Special Programs Administration (RSPA), DOT.

ACTION: Final rules; common preamble.

SUMMARY: This document is a common preamble to five alcohol misuse prevention program final rules being published by several operating administrations (OAs) of the Department of Transportation (FAA, FHWA, FRA, FTA, and RSPA) elsewhere in today's issue of the *Federal Register*. Four of these rules are required by the Omnibus Transportation Employee Testing Act of 1991. All of them will enhance the overall safety of the transportation industry and the public.

DATES: Effective March 17, 1994. See separate operating administration rules for specific effective and compliance dates.

FOR FURTHER INFORMATION CONTACT: Gwyneth Radloff, Office of the General Counsel, Department of Transportation, (202) 366-9305, 400 7th Street, SW., Washington, DC 20590, with respect to the overall Departmental effort. For information concerning a particular operating administration rule, contact the individual(s) listed under the **FOR FURTHER INFORMATION CONTACT** section for that rule.

SUPPLEMENTARY INFORMATION:**Summary**

FAA, FHWA, FRA, and FTA are promulgating rules to implement the Omnibus Transportation Employee Testing Act of 1991 ("the Act"), which requires alcohol and drug testing programs in the aviation, motor carrier, rail, and transit industries in the interest of public safety. FAA, FHWA and FRA also are relying on their other general safety authority as a basis for issuing these rules. RSPA is applying similar,

but more limited, requirements to the safety-sensitive employees in the pipeline transportation industry using existing statutory authority.

The five rules generally have the same requirements and common language to the extent possible, in recognition of the common elements of the statute and the problem being addressed. This will ease compliance for those companies, employers and third-party service providers that may be subject to, or performing testing under, the rules of more than one of the OAs. Intended substantive differences (where industry-specific differences are necessary or to comport with existing regulatory format or statutory requirements) are explained in the preambles to the individual OA rules.

In general, the rules prohibit covered employees from performing safety-sensitive functions: (1) When test results indicate an alcohol concentration of 0.04 or greater; (2) Within four hours after using alcohol; (3) While using alcohol on the job; (4) During the 8 hours following an accident if their involvement has not been discounted as a contributing factor in the accident or until they are tested; and (5) If they refuse to submit to required alcohol tests. Employers have to remove from a safety-sensitive function any covered employee who violates any of these prohibitions until he or she has met the conditions for returning to a safety-sensitive function. If an employee is found to have an alcohol concentration of 0.02 or greater but less than 0.04 or if the employee is under the influence of or impaired by alcohol, as indicated by behavior, speech and performance indicators of alcohol misuse, and a reasonable suspicion alcohol test result cannot be obtained, the employee will have to be removed from safety-sensitive duties for 8 hours or until a test result below 0.02 is obtained. Four of the rules require employers to conduct pre-employment, reasonable suspicion (the term used in the Act, which is comparable to the term "reasonable cause" testing used in the DOT OAs' existing drug rules and in the DOT advance notice of proposed rulemaking (ANPRM) on alcohol testing discussed below), post-accident, random, return-to-duty and follow-up alcohol testing. These rules also establish a performance standard for adjusting the initial 25 percent random alcohol testing rate for each transportation industry (except RPSA).

RSPA's rule requires only reasonable suspicion, post-accident, return-to-duty and follow-up testing. Most of RSPA's commenters opposed the proposed alcohol prevention program; others

supported it with various modifications tailored to the specific needs of the pipeline industry. Those in opposition noted that RSPA is not covered by the Act and that we do not have data indicating that there is a problem in the pipeline industry to support the costly imposition of the proposed program. They also perceived pipeline safety risks as different from those in other forms of public transportation, since pipelines do not carry people. Some commenters urged that we conduct a pilot program until we obtain sufficient data to make a decision on whether imposition of the program is justified.

The lack of data cited by some commenters could result as easily from the lack of testing and industry alcohol prevention programs as from the absence of an alcohol problem in the pipeline industry. Our primary job in these rules is to implement the Act, which we have done in the other four OA rules. But to be sure we are providing a margin of safety where the Act does not extend, we are establishing an alcohol prevention program, including reasonable suspicion and post-accident testing, for the pipeline industry. Pipeline safety, obviously, is very important. While pipelines do not carry people, they carry dangerous materials that could do tremendous damage to people and property if someone affected by alcohol makes mistakes. Therefore, for safety reasons, we have decided to impose an alcohol misuse prevention program on the pipeline industry. We will monitor the data from the testing that is conducted to determine whether any further action is warranted. The rule will still ensure that pipeline employees are subject to the same alcohol misuse prohibitions, consequences and educational efforts that apply to other transportation industry employees. Pipeline operators can, of course, conduct other types of alcohol testing under their own authority.

The rules will provide more flexibility to use different testing technologies for screening tests than we proposed in the OA notices of proposed rulemaking (NPRMs). When, in the future, we evaluate and approve a device as meeting NHTSA model specifications and we have established rules setting forth the procedures for its use, employers may use the device. However, at the present time, only evidential breath testing (EBT) devices on the National Highway Traffic Safety Administration's (NHTSA) Conforming Products List (CPL), including those without printers, meet these specifications and will have procedures in place at the time the five OA final

rules take effect. (58 FR 48705, September 17, 1993). The CPL is a list of alcohol breath testing devices that have been found to conform to NHTSA's Model Specifications for EBTs. The CPL serves as a guide to State and local governments when they make purchasing decisions about these devices. (NHTSA develops programs relating to motor vehicle and highway safety, some of which are designed to reduce alcohol and other drug use among drivers.) NHTSA has published elsewhere in today's **Federal Register** proposed model specifications for additional alcohol screening devices, which could lead to their approval for future use in conducting screening tests under these rules.

We also are considering requiring the employer to conduct a blood test in reasonable cause and post-accident situations where an EBT is not readily available. The blood alcohol testing proposal, including testing procedures, is addressed in a separate NPRM published elsewhere in today's **Federal Register**. Before we issue a final rule, we need to resolve specimen collection issues and determine how to identify those laboratories that we can rely on to accurately analyze blood samples for alcohol concentration.

All of the OA alcohol misuse prevention final rules also impose reporting and recordkeeping requirements and provide for dissemination of alcohol misuse information to employees, supervisor training, and referral of employees to substance abuse professionals (SAPs) for evaluation.

This document is a common preamble jointly issued by each of the five OAs and provides the background for and an overview of the general, common elements of their rules. It is incorporated as part of the preamble for each individual OA's rule; additional modal-specific preambles have been issued by each of the OAs to provide an explanation of any differences from, or additions to, the common language. The following related documents appear in today's **Federal Register**:

- (1) This common preamble;
- (2) An Office of the Secretary (OST) final rule on alcohol testing procedures and conforming changes to the existing drug testing procedures that is incorporated by reference into the OA alcohol misuse prevention final rules;
- (3) An Office of the Secretary (OST) NPRM proposing blood alcohol testing requirements and procedures that would be incorporated by reference into the OA alcohol misuse prevention final rules, if they become final;

(4) The modal-specific OA alcohol misuse prevention final rules for: FAA; FHWA (also includes changes to its existing drug rule mandated by the Act, including extension of its rule to persons required to hold a commercial drivers license (CDL), including intrastate truck and motor coach operations); FRA (also includes changes to its existing drug rule); FTA; and RSPA;

(5) FAA and FHWA NPRMs seeking public comment on application of alcohol and drug testing requirements to foreign operators in the United States in the aviation and motor carrier industries. A similar FRA ANPRM issued December 15, 1992, is being withdrawn by a notice published elsewhere in today's **Federal Register**. Foreign railroad operators have very limited operations in the U.S. and already comply with FRA's existing substance abuse requirements;

(6) An FTA final rule that imposes on recipients of Federal funding in the transit industry drug testing requirements similar to those in the other transportation industries (it also contains MIS requirements discussed below);

(7) An FAA NPRM proposing conforming changes to its existing drug testing rule to implement the requirements of the Act and for other purposes; and

(8) A DOT-wide common preamble with rule language from 6 OAs that proposes a performance standard for adjusting the random drug testing rate for the current random drug testing programs in the aviation, motor carrier, rail, pipeline and maritime industries and the new drug testing program for the transit industry. The proposals contain safeguards that would ensure maintenance of an adequate level of deterrence and detection of illegal drug use.

Related Management Information System (MIS) final rules issued by FAA, FHWA, FRA, RSPA and the U.S. Coast Guard (USCG) that require employers to submit annual drug testing program information (USCG rule also contains alcohol requirements) were published December 23, 1993 (58 FR 68194 *et seq.*). FTA's final drug testing rule contains its MIS requirements. Similar MIS programs for alcohol are established in the OA alcohol rules.

Regulatory assessments that analyze the costs and benefits of and the alternatives considered for each of the final rules and NPRMs published in today's **Federal Register** have been placed in the individual rulemaking dockets.

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Background

The Omnibus Transportation Employee Testing Act of 1991

On October 28, 1991, President Bush signed the Omnibus Transportation Employee Testing Act of 1991 ("the Act"). (Pub. L. 102-143, Title V). The Act requires the Department to prescribe regulations within one year that require testing of safety-sensitive employees in the aviation, highway, rail, and transit industries and in the Federal Aviation Administration for use, in violation of law or Federal regulation, of alcohol and drugs listed in the Controlled Substances Act. The Act preempts inconsistent State and local laws, except certain State criminal laws, in the aviation, highway, and transit industries and requires that the regulations be consistent with U.S. international obligations. It specifically mandates, among other things, privacy in collection techniques, incorporation of the Department of Health and Human Services' (DHHS) mandatory guidelines for drug testing and comparable safeguards for alcohol testing, quantified confirmation of any positive screening result, collection of split samples of body fluid specimens, confidentiality of test results, and scientifically-random selection of employees to be tested. It requires pre-employment, random, post-accident, and reasonable suspicion testing; periodic testing is discretionary. Regulations prescribed under the Act must include provisions for the identification of, and opportunity for treatment for, covered employees in need of assistance due to misuse of alcohol or illegal use of controlled

substances. The Act states that current Federally-mandated programs are unaffected by the new statutory requirements.

At the time of enactment of the Act, several OAs already had implemented programs designed to address the use and misuse of drugs and alcohol by transportation workers, and the Department had published an ANPRM to explore whether additional steps were warranted concerning alcohol misuse by employees in the DOT-regulated transportation industries (54 FR 46326, November 2, 1989). In 1988, six of the Department's OAs—FAA; FHWA; FRA; FTA (formerly the Urban Mass Transportation Administration, (UMTA)); USCG; and RSPA—issued drug testing rules for members of their regulated industries (53 FR 47002 et. seq., Nov. 21, 1988). (The FTA rule was vacated by a Federal appellate court in January 1990 on the grounds that the agency lacked statutory authority to issue nationwide standards requiring drug testing.) The drug testing rules generally apply to persons performing safety-sensitive functions in commercial transportation operations. The Department also published in 1988, and revised in 1989, a Department-wide drug testing procedures rule (49 CFR part 40) that governs testing under all the OA rules (53 FR 47002, Nov. 21, 1988; 54 FR 49854, Dec. 1, 1989). As noted above, the Act requires certain changes to the existing drug testing rules (e.g., it requires split samples and extends coverage to persons required to obtain a CDL, generally intrastate truck and motorcoach operations under the FHWA rule). It also directs FTA to issue a drug testing rule.

In addition to the requirements discussed above, the Act requires alcohol and drug testing for safety-sensitive FAA employees. Air traffic controllers are the largest group of employees subject to this testing (they are already subject to drug testing under an existing DOT policy). In addition, DOT employees and other Federal agency employees in positions requiring a CDL are subject to coverage under the FHWA rule. The Department will issue a DOT Order (an internal program document) to conform the Department's drug testing program for its own employees to the requirements of the Act and to implement a similar alcohol misuse prevention program.

Regulatory History

ANPRM

During the drug testing rulemakings, we noted that, although alcohol is a drug, the solution to the alcohol

problem may be very different from that concerning other drugs, such as cocaine or marijuana, and we would address it in a separate rulemaking. For that reason, with one exception, the OAs did not include alcohol among the list of substances to be tested for under the drug testing regulations. (The Coast Guard, which is not covered by this rulemaking, has mandatory post-accident alcohol testing and authorized reasonable cause (suspicion) alcohol testing. FRA had previously included alcohol in its post-accident testing mandate and had authorized alcohol testing for reasonable cause.)

On November 2, 1989, the Department published an advance notice of proposed rulemaking (ANPRM) to solicit public comment on whether the Department's existing regulatory requirements and programs were sufficient to respond to the hazards of alcohol misuse in DOT-regulated transportation industries and to determine what additional action, if any, should be taken. The ANPRM set forth a number of options for reducing alcohol misuse in DOT-regulated industries, if further action was deemed necessary. Over 225 comments were filed in response to the ANPRM; these comments were considered in developing the NPRMs.

The Public Hearing on Breath Test Device Capability

After the enactment of the Act, to enable better evaluation and comparison of the capabilities of different alcohol testing methods, the Department of Transportation conducted a public hearing on November 18, 1991, to obtain specific information from the manufacturers of breath test devices. Our purpose was to examine the current or feasible capabilities of equipment to handle the problems of testing in the transportation industry, particularly verification of the identity of tested individuals and the validity of the test result. At the hearing, the Department noted that attempts to tamper with the test and refusals to acknowledge the test result may be problems because an immediate result is available.

The Department also indicated that it would need to ensure accurate test results without adding prohibitive costs to any proposed program. Representatives of eight manufacturers assured DOT officials that existing technology can keep adequate, verifiable records of tests. They claimed that they could incorporate safeguards against tampering with adjustments to hardware and software, such as the assignment of a serial number to each test. They pointed out, however, that currently

available equipment alone cannot provide an indisputable verification procedure or replace trained human supervision of the testing process.

The Department believes that the testing procedures set forth in the separate final rule establishing new alcohol testing procedures for 49 CFR part 40 published in today's *Federal Register* provide adequate safeguards for breath testing in response to the above concerns.

The NPRMs

On December 15, 1992, the Department published eighteen separate documents, including fourteen NPRMs and four ANPRMs, that proposed programs in several DOT-regulated transportation industries to reduce alcohol misuse and to amend existing industry drug testing programs (57 FR 59382 *et. seq.*, December 15, 1992). These included: A common preamble and an OST NPRM on alcohol testing procedures and conforming drug testing changes (part 40), both of which were incorporated by reference into the FAA, FHWA, FRA (also included drug changes), FTA, and RSPA NPRMs proposing alcohol misuse prevention programs; FAA, FRA, and FHWA ANPRMs on application of these requirements to foreign operators in the United States; an FTA NPRM proposing an anti-drug program for the transit industry; FAA, FHWA, FRA, RSPA, and USCG NPRMs proposing the new MIS (FTA drug NPRM included its MIS proposal); an FHWA NPRM proposing statutorily-mandated changes to its existing drug rule, including extending coverage to intrastate truck and motorcoach operations; and a DOT-wide ANPRM that sought comment on less costly alternatives to the current industry random drug testing requirements, particularly changes to the random drug testing rate. The alcohol misuse prevention NPRMs proposed prohibitions on alcohol misuse, related consequences, several types of alcohol testing, reporting and recordkeeping requirements, dissemination of alcohol information, supervisor training and referral of employees to a substance abuse professional (SAP) for evaluation.

Summary of Comments

Since there are common requirements, bases and purposes for the rules, each DOT organization (term includes OAs and OST) involved may have relied upon comments submitted to the dockets of the other participating DOT organizations in developing its final rule. Where a DOT organization has relied upon a comment directed to

the docket of another DOT organization, it will make available a copy of that comment. Comments addressing issues common to all of the OAs' alcohol prevention programs generally are addressed throughout this common preamble. Comments on OA-specific issues and the draft economic analyses have been addressed in the preambles to the OA rules. Comments on testing procedures, foreign application, drug testing rules and the drug testing random ANPRM have been addressed in the preambles to those documents.

Approximately 700 comments were filed in response to the NPRMs in the various OA alcohol misuse prevention rule dockets. (Some commenters filed identical comments to more than one DOT organization.) Commenters included local, State and Federal governmental agencies, trade associations, employers, employees, labor unions, consortia, medical professionals, substance abuse professionals and individuals. Most of the comments were filed by employers, followed by trade associations and governmental bodies. The majority of the commenters had a mixed reaction to the proposed alcohol misuse prevention programs and suggested changes on a variety of issues. Some commenters applauded the efforts of Congress and the Department to reduce accidents and save lives by removing from our nation's transportation systems employees in safety-sensitive positions who misuse alcohol. However, approximately one-third of the commenters opposed the specific proposals and only a small percent (less than 5 percent) were enthusiastic about them. A significant number of those in opposition to this effort cited its high cost unsupported by data indicating that there is a serious problem in their industry. Other commenters did not believe that mandatory alcohol testing will effectively deter or eliminate alcohol use among covered employees. As discussed below, many of the requirements of these rules are mandated by the Act and the Department has no authority to modify or ignore them.

In addition to soliciting written comments, the Department held three public hearings on part 40 and the OA alcohol misuse prevention and anti-drug rules in Washington, DC; Chicago; and San Francisco in February and March 1993. OST and all OAs, except USCG, which proposed only MIS requirements, participated in these hearings. The hearings, which ran for two days in each location, consisted of one day of testimony on part 40 and general issues and a second day for breakout sessions

on OA concerns. Approximately eighty people presented testimony at those hearings. (Some commenters made presentations at more than one hearing.) Transcripts of all the hearings and any written materials submitted at the hearings are available in the appropriate rulemaking dockets. All comments received at those hearings have been fully considered in developing the final rules.

The Public Meeting

In February 1993, the Department held a public meeting to facilitate presentation and discussion of relevant information on workplace random testing and its impact on drug use deterrence. Over 20 participants presented papers and sparked discussions that ranged from mathematical models of drug testing rates and their impact on drug use to program data from corporations using random drug testing as part of a drug-free workplace strategy. The results of the meeting were inconclusive. The participants presented no definitive data that identified optimal random testing rates for achieving maximum deterrence of drug use. Many corporate representatives expressed views that favored reducing required random testing rates; however, they did not support their views with specific data on the causal or correlative relationship between random testing rates and drug use deterrence. The discussions also covered the corollary issue of detection of drug abusers who are not deterred by workplace drug prevention policies or programs. These issues also are relevant to alcohol random testing rates discussed later in this document.

The National Airline Commission

In April 1993, President Clinton established the National Commission to Ensure a Strong Competitive Airline Industry (also known as the National Airline Commission). Its charter was to review the financial condition of the airline industry and to make recommendations to assist the industry in recovering from the financial and operational difficulties it had faced during the last several years. The National Airline Commission met with industry, labor, and government representatives in a number of public meetings before drafting its final recommendations. Specific to this rulemaking, the Commission stated that "[n]ew pre-employment alcohol testing rules do not need to be adopted, and any random alcohol testing of airline employees should be at no more than a 10 percent rate."

The Existing Safety Problem

General Information and Definitions

Throughout this document, we have generally relied on or referred to the results of many studies concerning alcohol. Parenthetical references to these studies are included in the text; their full names are listed alphabetically in a bibliography in Appendix A. Copies of these studies have been placed in OST rulemaking docket 46574. It is important to note that the test data we have are not complete; often the database includes only those tests that were performed. Post-accident tests are conducted after some accidents, but not others, depending upon current regulatory requirements, the availability of testing personnel, and location and timing of accidents. When they are conducted, they may occur hours after the accident (e.g., in the railroad industry it takes an average of 5 hours before the post-accident tests can be conducted). Also, data are not comparable among the transportation modes, because of differences in reporting requirements, databases, and time periods. In addition, the referenced studies generally used different parameters and are therefore not comparable to each other.

Many of the words relating to alcohol are used interchangeably in our society, which may cause some confusion. In this document, we use the terms "driving while intoxicated" (DWI) and "driving under the influence" (DUI) to refer to the same thing: Violation of State and/or Federal alcohol concentration standards defining intoxication. "Zero tolerance" refers to an alcohol concentration standard of 0.00, or in some cases, 0.01 or 0.02. Limits on current testing technology establish the limit of detection at 0.02 concentration for accuracy and precision. "Impairment" and "under the influence" refer to the effect of alcohol ingestion on the performance of a safety-sensitive function, without regard to a specific alcohol concentration.

The Effects of Alcohol

The potential effects of alcohol misuse are substantial in terms of lives lost, injuries and environmental and property damage. Alcohol misuse claims at least 100,000 lives annually, 25 times as many as all illegal drugs combined. In 1992, 39,235 deaths occurred on our nation's highways, of which 36 percent involved a legally intoxicated driver or non-occupant (e.g., pedestrian), and another 9 percent involved a driver or non-occupant with at least some alcohol (with an alcohol concentration over 0.01). Alcohol is

involved in 45 percent of total highway fatalities. (National Highway Traffic Safety Administration, "Traffic Safety Facts 1992—Alcohol").

Ethanol (the psychoactive component of alcoholic beverages) is a central nervous system depressant. It has been widely recognized for years that consumption of alcohol can degrade performance of demanding or delicate tasks. There is less agreement, however, about how much alcohol must be ingested before a significant degradation of performance occurs. Studies have indicated that the effects of alcohol vary among individuals, and, even for a given individual, alcohol will have varying effects depending on such factors as motivation, fatigue, and previous experience with alcohol (Zero Alcohol, 1987; Ryder, 1981; Landauer, 1983; Lister, 1983). One reason for the substantial variation among individuals is that ingestion of a specified quantity of alcohol by two people will not necessarily produce the same alcohol concentration in each, even if they have the same body weight (Zero Alcohol, 1987).

In one study, for example, it was found that a given body-weight-adjusted dose of ethanol could produce a range of alcohol concentrations of 0.036 to 0.095 (O'Neill, 1983). In addition, alcohol appears to enter the blood stream at different rates in different people (Zero Alcohol, 1987). In another study, subjects were given controlled doses and had equal amounts of food in their system. Nevertheless, the time required to reach the peak alcohol concentration varied from 15 to 90 minutes after ingestion (Wilson, 1984).

There also are performance differences between individuals that are unrelated to their blood alcohol concentration. It appears that highly skilled professionals may be better able to compensate for the physiological effects of alcohol than persons who are less skilled, particularly at lower alcohol concentrations. In two studies comparing the effect of alcohol on the performance of racing drivers and ordinary drivers on a closed track, the skill of the ordinary drivers showed some degradation at an alcohol concentration of 0.05, while the racing drivers showed no impairment until they reached substantially higher alcohol concentrations (Forney, 1961). Similarly, in a comparison of nonprofessional and professional pilots at alcohol concentrations of 0.04, 0.08, and 0.12, the nonprofessionals made numerous errors in tracking, while the professionals' tracking ability did not decrease even at the highest alcohol concentration (Billings, 1972). The

study noted, however, that the professional pilots committed more procedural errors than normal after alcohol consumption. Compounding factors, such as fatigue and unexpected challenges, also are likely to affect results in a real-world situation.

Most States have adopted an alcohol concentration of 0.10 as the definition of intoxication in connection with laws imposing civil or criminal penalties for driving under the influence for non-commercial as well as for commercial operators. Some use it as a rebuttable presumption of a violation; others as a *per se* violation. Ten states have lowered their alcohol concentration standards to 0.08; and a number of states have adopted or are in the process of considering adoption of the existing 0.04 FHWA alcohol concentration standard for commercial drivers established by previous rulemaking. States with alcohol concentration standards for operating recreational vessels or aircraft typically use 0.10.

As indicated above, however, a number of laboratory studies have shown that performance on some tasks can begin to degrade at alcohol concentrations well under 0.10 (Moskowitz, 1973; Drew, 1959; Landauer, 1983; NHTSA, 1988). Some studies have suggested that performance degrades in a linear fashion, beginning with the lowest levels tested (Moskowitz, 1985; Drew, 1959). Blood alcohol concentrations (BAC) lower than 0.05 have been associated with increases in errors in tasks requiring divided attention, and it appears that cognitive performance is decreased for most individuals at BAC's of 0.04 or less (Zero Alcohol, 1987; Evans, 1974). Low alcohol concentrations have also been shown to affect a driver's stopping distance and to increase errors in steering (Laurell, 1977). There is no definitive answer to how much the risk of accident occurrence increases as a result of the performance deficit, but some relationship can be assumed. Those OAs in the Department that have set existing alcohol concentration standards for transportation workers (FAA, FHWA, FRA and Coast Guard) generally have used 0.04 as the prohibited concentration.

In its most recent edition of "Fatality Facts," the Insurance Institute for Highway Safety notes that "even at BACs as low as 0.02%, alcohol affects driving ability and crash likelihood. The probability of a crash begins to increase significantly at 0.05% BAC and climbs rapidly after about 0.08%. For drivers with BACs above 0.15% on weekend nights, the likelihood of being killed in a single-vehicle crash is more than 380

times higher than it is for nondrinking drivers."

The Alcohol Problem—Generally

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) reported in 1987 that two of every three adults in the United States drink, but 10 percent of those drinkers consume half of the nation's beer, wine and liquor. The National Institute on Drug Abuse (NIDA) reported that an estimated 17 million U.S. adults are alcoholics, which is about six times higher than the number of cocaine users. (NIDA study, 1989). While it is difficult to estimate the precise cost to society from alcohol misuse, there is no doubt that the cost is enormous. The potential effects of alcohol misuse are substantial in terms of lives lost, personal injuries, property damage, business losses (lost productivity, absenteeism, increased health care costs, etc.) and environmental damage.

According to a Research Triangle Institute study performed for the Department of Health and Human Services, the overall economic cost to American society from alcohol misuse was \$89.5 billion in 1980. This amount represents direct costs, such as medical treatment, and indirect costs, such as lost wages and reduced productivity. In 1987, the NIAAA estimated the economic costs to society of alcohol misuse to be nearly \$117 billion a year, including \$18 billion from premature deaths, \$66 billion in lost productivity, and \$13 billion for rehabilitation. Assuming the base numbers are still the same, inflation presumably has increased the cost in current dollars.

The National Academy of Sciences (NAS) recently released a study of drug use in the American workforce. The study reviewed the existing research literature on (1) the effects of drug and alcohol use on workplace performance and productivity, (2) the effectiveness of workplace interventions, and (3) the scope of alcohol and other drug use. The study concluded that more epidemiological and longitudinal research is needed and that the current research literature does not provide definitive conclusions about the scope of use, the specific effects of drug and alcohol use on work performance tasks, and the effectiveness of workplace interventions such as drug and alcohol testing and employee assistance programs. We believe that the existing research literature supports the actions that we are taking here and that data gathered as a result of these rules will provide useful additional information concerning these issues.

National Health Care Reform

Secretary of Transportation Federico Peña recently set a goal of reducing alcohol-related highway fatalities from 45 percent to 43 percent of total highway fatalities by 1997. He noted that alcohol-related traffic fatalities decreased by 20 percent between 1990 and 1992 due to increased alcohol awareness among teenagers and tougher enforcement measures that reduced impaired driving by repeat offenders. Motor vehicle accidents are a major health problem. They are the primary cause of death for the American population between 5 and 34 years of age, and account for half the total of injury deaths. More people are injured or die in motor vehicle-related accidents each year than from heart disease, cancer, and strokes combined. Alcohol involvement is the single largest factor in motor vehicle deaths and injuries, which as a whole cost the nation \$14 billion in health care costs each year; any reduction in impaired driving would directly contribute to reducing health care and other economic costs. The Department estimates that reducing highway alcohol-related fatalities to 43 percent of total fatalities and reducing related injuries by a proportionate amount would save 1,200 lives annually and save U.S. taxpayers \$282 million in health care costs annually. Obviously, reducing alcohol-related fatalities and injuries in other transportation industries would further reduce those costs.

The measures contained in these rules and the Department's partnership with industry and State and local governments to educate the public about impaired driving are part of a broad Department effort to reduce accidents and injuries resulting from alcohol misuse in each of the transportation industries, which will, in turn, reduce health care costs under President Clinton's health care reform initiative. Increased detection of alcohol misusers and their diversion into the health care system could increase health care costs in the short term, since individuals with serious alcohol problems tend to neglect health care until intervention. This increase would be mitigated to a certain extent by a decrease in alcohol-related absenteeism. However, long term health care costs should decrease because early intervention prevents more serious and more costly health problems later.

Alcohol Misuse in the Transportation Industry

General

The Department's previous alcohol misuse prevention efforts have

developed unevenly and vary across the transportation industries. The existing OA rules focus on alcohol in terms of: Its effect on an individual's medical qualifications; prohibitions against on-duty use; operating while under the influence; use during defined pre-duty periods; and sanctions for violations of the Federal regulatory scheme, as well as sanctions for violations of State alcohol laws. Alcohol testing, with limited exceptions, has been left to State enforcement. (Current FRA rules require post-accident and authorize reasonable cause testing. The FAA requires crewmembers to submit to tests upon request by State and local officials and to furnish the results to the Administrator. The Coast Guard also has existing requirements concerning alcohol misuse, including some testing.) Each of the following sections briefly describes the existing OA rules on alcohol and contains available Departmental data on the alcohol problem in each segment of the transportation industry.

Aviation

The current FAA regulations prohibit a person from acting or attempting to act as an aircraft crewmember if he or she is under the influence of alcohol, has consumed any alcoholic beverage within the prior 8 hours, or has an alcohol concentration of 0.04 or greater. The FAA may medically disqualify a pilot with a history of drug dependence, alcoholism, or mental problems.

In 1987, the Department's Inspector General checked the National Driver Register (NDR) against records in the Florida Department of Motor Vehicles; it found that nearly 8,000 FAA-certified pilots in Florida had been convicted of drunk-driving offenses. Recent legislation allowed FAA and the rail industry to use the NDR to locate and review individual driving records to screen qualifications of airline pilots and locomotive engineers. The FAA was unaware of these DUI convictions because the pilots had not reported them to the FAA as required. The FAA then issued a DUI enforcement policy and a rule that includes, among other matters, a process for examining driving records. Pilots with 2 or more drug- or alcohol-related driving offenses within 3 years are subject to FAA certificate revocation action.

In 1991, the FAA began checking the NDR to identify pilot certificate holders who had drunk-driving convictions. Of pilots seeking medical recertification during the period May 1991 through May 1993, 5.79 percent had at least one DWI conviction reported. The total number of pilots (for scheduled and

non-scheduled airlines) who had one or more DWI's was 4,386, or 6.4 percent. There is no research that directly links impaired driving behavior to commercial aviation performance; however, impaired driving behavior is often associated with alcohol abuse and/or alcoholism.

There has never been an accident involving a large U.S. passenger airline in which the probable cause was attributed to alcohol use. However, in 1990, three Northwest Airlines pilots were convicted of flying while intoxicated between Fargo, ND, and Minneapolis, MN. Two hours after the flight ended, the crew captain's alcohol concentration was found to be 0.13; he testified that he drank 20 rum and cokes the night before the 6 a.m. flight. Starting in the early 1970's, the Air Line Pilots Association and the major airlines, in cooperation with the FAA, developed a program to identify alcoholic pilots, so that they could be treated and, as appropriate, returned to duty. More than 1,500 pilots have been through this program, with a relapse rate of approximately 10 percent. Since the program provides for stringent surveillance of treated pilots, there has been no compromise of safety. Nevertheless, the existence of such an extensive program and the occurrence of the Northwest pilots incident demonstrate that the air carrier industry is not immune to the problem of alcohol misuse.

The National Transportation Safety Board (NTSB) has collected the following data concerning the relationship between alcohol and aviation accidents: From 1975 through 1986, eleven part 135 carriers (all except one were commercial air taxi cargo planes; the exception was a non-scheduled charter carrier with a foreign crew) were involved in accidents in which alcohol was determined to be a factor. As noted above, there have been no part 121 or part 135 (large or air taxi/commuter air carrier) accidents in which alcohol has been determined to be a cause.

Virtually all commenters to the FAA docket claimed that, in light of the current financial state of the airline industry, DOT should not mandate an overzealous random alcohol testing program that is not statistically justified. As we noted above, we are constrained by the requirements of the Act. To the extent possible, we have tried to provide flexibility to employers that will enable them to make cost-conscious decisions for their specific circumstances. With respect to our lack of data, it is difficult to know whether the lack of a large U.S. passenger aircraft accident caused by

alcohol is due to the fact that it has never happened or because we have no required testing and could not determine that alcohol was involved.

Motor Carriers

Currently, drivers found to be under the influence of alcohol or drugs are disqualified from operating a commercial motor vehicle (CMV). FHWA regulations prohibit the use of alcoholic beverages within four hours of reporting to work and also prohibit a driver from driving while having any measurable alcohol concentration or any detected presence of alcohol in his or her system. This effectively amounts to a zero alcohol limitation for CMV operators. In addition, a driver will not be considered physically qualified to drive a motor vehicle if, among other things, the driver has no current clinical diagnosis of alcoholism.

Accident statistics indicate that nearly half of the fatally injured noncommercial motor vehicle drivers had a measurable amount of alcohol in their blood (usually 0.10 or more) compared with about 15 percent of fatally injured drivers of medium and heavy trucks. Moreover, as the chart below indicates, for those truck drivers who had been drinking before an accident, the highest accident rate was among those consuming the most alcohol. Drivers of heavy and medium trucks with measurable alcohol concentrations are involved in about 750 fatal crashes annually, along with another 7,700 crashes resulting in personal injuries and 4,750 crashes involving only property damage (Zero Alcohol, 1987).

	Percentage of all fatal truck accidents	Percentage of the 15% of truck drivers who had alcohol in their blood
No Truck Driver Use of Alcohol	85.0	N/A
AC=0.10 or more	9.1	60
AC=0.04-0.10 ..	2.7	18
AC=.03 or less ..	3.2	21

(Zero Alcohol, 1987) (FARS data tapes, 1982-1985) (AC means alcohol concentration)

In 1990, the NTSB published the results of a study of alcohol (and other drugs) used by CMV operators in fatal-to-the-driver, heavy truck accidents. Thirteen percent of the fatally injured drivers tested positive for alcohol. (Another 20 percent of the drivers tested positive for other drugs.) We also know that the cost of accidents to employers is substantial, over and above the lives

lost, whether CMV accidents are caused by alcohol or something else. The National Safety Council estimates that an on-the-job accident is four times more costly than one that occurs in a personal vehicle, with an average cost to employers of \$168,000 for a fatal accident and \$6,900 for a non-fatal accident. The impact of on-the-job accidents caused by alcohol on employer costs is quite significant.

FHWA Pilot Project. The Act required the Secretary of Transportation to conduct a pilot program for the purpose of testing drivers on a random basis to determine if a driver has used alcohol or a controlled substance in violation of law or federal regulation. The pilot testing program was administered as part of the FHWA's Motor Carrier Safety Assistance Program (MCSAP) and implemented in four States for a period of one year. At the completion of the pilot program, the Department will issue a report of the program, including recommendations concerning the desirability and implementation of a MCSAP-administered random testing program. FHWA began the implementation of the required pilot project in Fiscal Year 1993 (October 1, 1993-September 30, 1994). (N.B.: the Fiscal Year for the Federal government may differ from that used by other entities.) Preliminary data from the pilot program show 88 breath test results of 0.02 alcohol concentration or greater out of 43,170 tests conducted (0.2 percent). However, in two States (Minnesota and New Jersey) submitting to the breath test was voluntary and from 5 to 10 percent of drivers randomly selected declined to take a breath test.

Rail

Current FRA regulations prohibit on-the-job use of, possession of, or impairment by, alcohol, or having an alcohol concentration of 0.04 or more, for employees covered by the Hours of Service Act. Workers who report for duty under the influence can be identified, removed from the workplace, and referred for assistance under Operation RedBlock or other similar peer prevention substance abuse programs operated by the railroad industry. The covered employee can be referred for assistance by a peer, a supervisor or himself/herself.

As part of the post-accident testing conducted under its current rules, FRA has gathered the following data. From February 1986, when mandatory FRA post-accident blood testing for alcohol began, through December 1992, 23 employees tested positive for alcohol (0.5 percent of employees tested). However, the number of positive

findings has declined from 6 (1.0 percent of all persons tested) in 1989, to 1 (0.3 percent of all persons tested) in 1992. Since 1986, alcohol appears to have played a causal role in 11 accidents/incidents involving four deaths, three injuries, and property damage in excess of \$3.3 million. In one, the engineer tested positive at an alcohol concentration of 0.16, and alcohol was found by the NTSB to be a contributing factor to the accident. The incident caused \$1.58 million damage and the death of the engineer. In another accident, eight injuries and \$194,000 in damages resulted, and a dispatcher tested positive at 0.15 alcohol concentration. In a 1990 accident, an engineer tested positive with an alcohol concentration of 0.05 after his train passed a stop signal and collided with another train, resulting in one injury and nearly \$500,000 in property damage. In 1991, two brakemen were killed, one by a train when struck during a switching operation and the other when he fell from the side of a train. Post-mortem toxicology revealed alcohol concentrations of 0.04 and 0.08, respectively.

Reasonable cause breath testing under the FRA program or pursuant to railroad authority (triggered by rule violations, less serious accidents and injuries, or reasonable suspicion) has produced the following results: 11 of 348 persons so identified tested positive in 1986 (3.2 percent); 24 of 593 tested positive in 1987 (4.0 percent); 46 of 1005 tested positive in 1988 (4.6 percent); 31 of 973 tested positive in 1989 (3.2 percent); 32 of 2662 tested positive in 1990 (1.2 percent); 37 of 2798 tested positive in 1991 (1.32 percent); and 30 of 2850 tested positive in 1992 (1.2 percent). FRA regulations define a "positive" breath test as one indicating an alcohol concentration of 0.02 or above. The significance of these results with respect to measuring prevalence in the population is difficult to determine. It should be expected that a higher percentage of reasonable suspicion tests will be positive, since prohibited use or impairment had already been identified or suspected.

Transit

FTA does not have any existing regulations concerning alcohol. Its primary mission is to provide grants for the financing and improvement of transportation systems. Many of FTA's grantees, however, are subject to other Federal requirements on alcohol use. All commuter rail operations funded by FTA, for example, are subject to FRA regulations. Ferry operations that receive FTA funds are subject to USCG

safety, drug and alcohol regulations, as well as the FTA drug and alcohol testing rules published today.

The need for alcohol testing of transit employees was highlighted by a December 28, 1990, accident in Boston, Massachusetts, where a transit operator, with an alcohol concentration above 0.10, crashed a trolley car, injuring 33 people. In addition, the Senate Committee on Commerce, Science, and Transportation's report on S. 676, No. 102-54 (May 2, 1991), noted that, in Philadelphia alone, transit operators have tested positive for drug or alcohol use in six major accidents between 1986 and 1990, involving at least 183 injuries and three deaths. (Separate figures for drug and alcohol involvement were not provided.) On August 28, 1991, a New York City Transit Authority motorman later found to have an alcohol concentration of 0.21 crashed a subway train resulting in 5 deaths and 171 injuries; this accident led to the prompt passage of the Act. Following issuance of the 1988 FTA anti-drug rulemaking, some industry members indicated that alcohol is a more serious problem than drugs.

An FTA document entitled, "Substance Abuse in the Transit Industry," November 1991, was based upon a transit agency survey and an employee survey. It revealed that responding transit managers perceived alcohol as the major substance of misuse and that 58 percent of the transit systems test for alcohol. Employee knowledge of coworker alcohol misuse was extensive; about 70 percent of employees surveyed had some knowledge, either through hearsay or by direct observation, of alcohol impairment of colleagues in the workplace during the previous year. About six percent of the safety-sensitive employees reported alcohol use during or just before duty. Another 15 percent of the safety-sensitive employees reported less frequent alcohol consumption, but at a nearly similar volume as those employees noted above. When comparing these data with those contained in the "National Household Survey on Drug Abuse: Population Estimates 1988" and the comparable 1990 NIDA survey, it appears that reported alcohol use in the transit industry is slightly lower than that reported for the general population.

Pipeline

RSPA has no specific regulations on alcohol. It does have a general regulation on health of pipeline workers at liquefied natural gas plants. Pipeline operators must look for any physical condition that would impair

performance, including any observable disorder or condition that is discoverable by a professional examination.

We have no specific data on alcohol-related accidents or lost productivity data in this area; however, a number of the commenters in the anti-drug rulemaking seemed to believe that alcohol is a more pervasive problem than drugs in the pipeline industry. We also are aware that many companies in the pipeline industry are known to have alcohol prevention programs. We do not have statistics or data on the prevalence of the problem in the industry, but we cannot assume that pipeline workers are immune from the problem and must err on the side of safety. The largest single cause of pipeline accidents is excavation damage by people digging into pipelines (people not regulated by RSPA).

Legal Authority/Issues

Background

The following legal analysis was included in the common preamble to the proposed DOT alcohol testing rules published in the *Federal Register* of December 15, 1992, (See 57 FR 59389-59391) and is republished with this document for ease of reference. Since that time, there have been no significant case law developments to raise any doubts concerning the Department's stated belief that existing legal precedents support this rulemaking. To the contrary, the case law addressing the constitutionality of alcohol and drug testing is even more settled. Of particular note in this regard is a recent Federal district court ruling that random testing of commercial motor vehicle operators for alcohol and controlled substances pursuant to a one-year pilot study in four States, as mandated by section 5(b) of the Omnibus Transportation Employee Testing Act of 1991, Pub. L. 102-143, title V, codified at 49 U.S.C. app. 2717 note, comports with the Fourth Amendment of the U.S. Constitution and is not an unreasonable search and seizure. *Owner-Operator Independent Drivers Association, Inc. v. Peña*, No. 93-1427, U.S. District Court for the District of Columbia, November 1, 1993.

General

The Omnibus Transportation Employee Testing Act of 1991 is a direct statutory mandate for alcohol testing in the aviation, motor carrier, rail, and transit industries. In addition to this authority, the general safety authority relied on for issuing the drug testing rules described above also provides a

basis for issuing alcohol misuse prevention rules by FAA, FHWA, FRA, and RSPA. Although the existing case law addressing the constitutionality of employee alcohol testing programs remains more sparse than that for drug testing, the existing legal precedents support this rulemaking effort to require alcohol testing in the regulated transportation industries.

Consistent with court findings in the area of government-mandated drug testing of employees, alcohol testing mandated by the government is considered a search within the meaning of the Fourth Amendment to the U.S. Constitution. See, *Schmerber v. California*, 384 U.S. 757, 767-768 (1966) ("compelled intrusions into the body for blood to be analyzed for alcohol content" must be considered a Fourth Amendment search); *Skinner v. Railway Labor Executives' Association*, 489 U.S. 616-617 (1989) ("Subjecting a person to a breathalyzer test, which generally requires the production of alveolar or 'deep lung' breath for chemical analysis * * * implicates * * * concerns about bodily integrity and, like the blood-alcohol test * * * considered in *Schmerber*, should also be deemed a search.")

In deciding whether a particular search comports with Fourth Amendment protections, courts must determine that under all the particular circumstances the search itself is "reasonable." As the leading case on bodily fluid testing, *Skinner*, makes clear, issuance of a warrant or the existence of probable cause or individualized suspicion is not a minimum essential requirement in establishing the reasonableness of a search under an administrative testing program.

In *Skinner*, the Supreme Court upheld regulations issued by the Federal Railroad Administration governing drug and alcohol post-accident and reasonable cause testing of railroad employees (49 CFR part 219). The Court concluded that the testing procedures and methods of procuring blood, breath, or urine for testing as set forth in subparts C and D of the FRA regulations "pose only limited threats to the justifiable expectations of privacy of covered employees." 489 U.S. at 628. In specifically focusing on the privacy implications of breath alcohol tests, the Court also pointed out that:

The breath tests authorized by subpart D of the regulations [testing for reasonable cause] are even less intrusive than the blood tests prescribed by subpart C [post-accident toxicological testing]. Unlike blood tests, breath tests do not require piercing the skin and may be conducted safely outside a

hospital environment and with a minimum of inconvenience or embarrassment. Further, breath tests reveal the level of alcohol in an employee's bloodstream and nothing more. Like the blood-testing procedures mandated by Subpart C, which can be used only to ascertain the presence of alcohol or controlled substances in the bloodstream, breath tests reveal no other facts in which the employee has a substantial privacy interest. * * * In all the circumstances, we cannot conclude that the administration of a breath test implicates significant privacy concerns. *Id.* at 625-626.

While the Court indicated that the collection of urine samples requires employees "to perform an excretory function traditionally shielded by great privacy, [thus] rais[ing] concerns not implicated by blood or breath tests[.]" it pointed out that the FRA collection procedures significantly reduced the degree of personal privacy intrusion. *Id.* at 626. The Court also examined the overall privacy expectations of covered railroad workers subject to the FRA testing requirements. It concluded that these expectations "are diminished by reason of ['covered employees'] participation in an industry that is regulated pervasively to ensure safety * * *." *Id.* at 627.

By contrast, the Court found that the government's interests in seeking to determine the cause of an accident or incident, deterring alcohol and illegal drug use by rail employees, and safeguarding the general public are compelling. Under these circumstances, the Court held that alcohol and drug testing pursuant to the FRA regulations are reasonable within the meaning of the Fourth Amendment. Also, the Court found that the government's justification in testing for misuse of alcohol—a legal substance—was entitled to no less weight than its justification for testing for drugs, the possession of which is unlawful. Thus, as the Court pointed out, the FRA-prescribed toxicological tests were not designed "to assist in the prosecution of employees, but rather to prevent accidents and casualties in railroad operations that result from impairment of employees by alcohol or drugs." *Id.* at 621-622, 633 (quoting FRA regulations at 49 CFR 219.1(a)).

The alcohol testing requirements for transportation industry workers published by each of the OAs in today's *Federal Register* are consistent with the Court's views in *Skinner*. Given the overwhelming public safety considerations associated with alcohol testing programs and the limited degree of intrusion into individual privacy interests engendered by the tests, the required testing programs would be

constitutionally permissible under the Fourth Amendment.

Also, the requirement that an employer perform random alcohol testing that is performance-related, i.e., related closely in time to an employee's actual performance of safety-related duties, further demonstrates the reasonableness of the rules for Fourth Amendment purposes by ensuring that testing for misuse of alcohol is clearly related to the employee's performance of these duties. With respect to use of particular testing devices or methods, we note that, as a number of courts have pointed out, the reasonableness of a testing program does not necessarily turn on the existence of other alternatives that might be less intrusive. See *American Federation of Government Employees v. Skinner*, 885 F.2d 884, 897 (1989), cert. denied, 495 U.S. 923-924 (1990).

The lack of a demonstrated substance abuse problem among the workforce in a particular industry should not, of itself, pose insurmountable constitutional impediments to a testing program for that workforce. This point was made clear by the Supreme Court in *National Treasury Employees Union v. Von Raab*, 489 U.S. 656, 674-675 (1989), which was decided the same day as *Skinner*. In *Von Raab*, the Court upheld urinalysis testing for illegal drugs of U.S. Customs Service employees slated for promotions into positions that involved either interdicting illegal drugs or carrying a firearm. Despite the Commissioner of Customs' stated belief that "Customs is largely drug-free," the Court concluded that there was little reason to suspect that the Customs Service was "immune" from society's pervasive drug abuse problem and held that the testing program was constitutionally defensible as a means to ensure that employees promoted to these sensitive positions are drug-free. *Id.*, at 660, 674. It stated that the government does not have to first establish that a specific industry has a problem. ("It is sufficient that the government have a compelling interest in preventing an otherwise pervasive societal problem from spreading through the particular context.") *Id.* note 3 at 675.

Skinner and *Von Raab* established the analytical framework for courts to resolve constitutional challenges to various employee substance abuse testing programs. Not surprisingly, Federal courts reviewing anti-drug abuse regulations issued by the Department have relied extensively on these two decisions in upholding drug testing of safety- and security-sensitive workers in industries regulated by the

Department. See, *Bluestein v. Skinner*, 908 F.2d 451 (9th Cir. 1990), cert. denied, 111 S.Ct. 954 (1991) (upholding constitutionality of Federal Aviation Administration regulations requiring random drug testing of flightcrew members, maintenance personnel, and other categories of employees in the commercial aviation industry); *International Brotherhood of Teamsters v. Department of Transportation*, 932 F.2d 1292 (9th Cir. 1991) (upholding constitutionality of Federal Highway Administration regulations requiring random, biennial, pre-employment and post-accident drug testing of commercial motor vehicle drivers operating in interstate commerce); *Railway Labor Executives' Association v. Skinner*, 934 F.2d 1096 (9th Cir. 1991) (upholding constitutionality of Federal Railroad Administration's regulations requiring random drug testing of railroad workers in safety-sensitive positions); *International Brotherhood of Electrical Workers v. Skinner*, 913 F.2d 1454 (9th Cir. 1990), and *United Steelworkers of America v. Skinner*, 768 F. Supp. 30 (D. RI 1991) (upholding constitutionality of Research and Special Programs Administration's regulations requiring random, pre-employment, and post-accident drug testing of safety-sensitive employees engaged in natural gas, liquefied natural gas, and hazardous liquid pipeline operations.) See also, *Transportation Institute v. Coast Guard*, 727 F. Supp. 648 (D.D.C. 1989) (upholding constitutionality of Coast Guard regulations requiring pre-employment, periodic, post-casualty, and reasonable cause drug testing for merchant marine personnel; however, regulations requiring random drug testing of all vessel crewmembers were found to violate the Fourth Amendment because the safety-sensitive duties performed by this entire class of employees was not evident. Although the court noted that random testing for employees could be constitutionally acceptable, it held that the Coast Guard had not adequately described the safety-sensitive functions of the covered employees to allow the court to establish the necessary nexus. The missing safety nexus was established in a subsequent Coast Guard final rule reimplementing random drug testing). Even pre-*Skinner* and *Von Raab* court decisions addressing the constitutionality of various employee alcohol testing programs have concluded that such testing comports with the Fourth Amendment. Thus, a State regulation requiring jockeys to submit to mandatory warrantless breath alcohol tests on each racing day was

found to be constitutionally permissible. *Shoemaker v. Handel*, 795 F.2d 1136 (3d Cir.), cert. denied, 479 U.S. 986 (1986). Similarly, alcohol and drug testing during a pre-employment physical examination, work-related examination, return to work after unscheduled absence, or on the basis of reasonable suspicion or involvement in an accident or incident was upheld in the case of transit employees directly involved in the operation, maintenance, and decisionmaking of a public transit system. *Amalgamated Transit Union, Local 933 v. City of Oklahoma City*, 710 F. Supp. 1321 (W.D. Okla. 1988). *Accord, Amalgamated Transit Union, Division 1279 v. Cambria County Transit Authority*, 691 F. Supp. 898 (W.D. Pa. 1988) (mandatory drug and alcohol testing during annual physical examination does not violate Fourth Amendment).

Also, several more recent Federal court decisions upheld employee alcohol testing in the wake of *Skinner*. Thus, in *Transport Workers Union, Local 234 v. Southeastern Pennsylvania Transportation Authority*, 863 F.2d 1110 (3d Cir. 1988), vacated and remanded, 492 U.S. 902 (1989), *aff'd on remand sub nom. United Transportation Union v. Southeastern Pennsylvania Transportation Authority*, 884 F.2d 709 (1989), the U.S. Court of Appeals for the Third Circuit upheld, inter alia, random breath testing of transit operating employees. See also, *Tanks v. Greater Cleveland Regional Transit Authority*, 930 F.2d 475 (6th Cir. 1991) and *Holloman v. Greater Cleveland Regional Transit Authority*, 741 F. Supp. 677 (N.D. Ohio 1990), *aff'd*, 930 F.2d 918 (6th Cir. 1991) (upholding transit authority's drug and alcohol testing program requiring testing of blood, saliva, and urine in the face of challenges by two bus drivers subjected to random, post-accident, and periodic testing); *Moxley v. Regional Transit Services*, 722 F. Supp. 977, 980 (W.D. NY 1989) (upholding constitutionality of transit authority's drug and alcohol testing program and noting that "the Government's interest in the efficient and proper operation of the workplace is at a zenith where public's [sic] lives depend on the reliable and sober performance of Government employees").

Consistent with the Supreme Court's analysis in *Skinner* and *Von Raab* and lower court decisions, if the Congress determines that there is a need for properly-administered alcohol testing to ensure that employees in transportation industries are not adversely affected by alcohol while performing safety-sensitive functions, that need would

outweigh the privacy interests of these employees and, thus, would be constitutionally permissible.

The Americans with Disabilities Act and DOT Drug and Alcohol Testing

The Americans with Disabilities Act of 1990 (ADA) (Pub. L. 101-36) does not, in any way, preclude or interfere with employers' compliance with the Department's new or existing drug and alcohol testing regulations. However, title I of the ADA, which prohibits discrimination against a "qualified individual with a disability," may affect the personnel actions an employer might wish to take with respect to some individuals who test positive for alcohol or drugs or otherwise violate the prohibitions of the Department's drug and alcohol rules.

Title I covers employers who have fifteen or more employees for more than 20 calendar weeks in a year (section 101(5)(A)). (Until July 26, 1994, only employers with 25 or more such employees are covered.) Covered employers may not discriminate against a qualified individual with a disability with respect to applications, hiring, advancement, discharge, compensation, or other terms, conditions or privileges of employment (section 102(a)).

Before discussing the effect title I may have on employer personnel actions following a positive DOT-mandated drug or alcohol test or other violations of DOT drug and alcohol rules, it is important to note the specific ADA provisions that address DOT drug and alcohol rules. The ADA specifically authorizes employers covered by DOT regulations to require their employees to comply with the standards established in those regulations, including complying with any rules that apply to employment in safety-sensitive positions as defined in the DOT regulations. (section 104(c)(5)(C)). By authorizing employers to require employees to comply with the standards in DOT rules, this provision authorizes compliance not only with testing provisions of the rules but also of other drug and alcohol-related provisions that affect safety-sensitive employees (e.g., pre-duty abstinence, on-the-job use). The legality under the ADA of employer compliance with DOT drug and alcohol requirements other than those concerning testing is underlined by several other provisions of title I. An employer may prohibit the use of drugs and alcohol in the workplace, may require that employees not be under the influence of alcohol or be engaging in the illegal use of drugs in the workplace, and may require that employees conform to the requirements of the

Drug-Free Workplace Act (Pub. L. 100-690, title V, subtitle D) (section 104(c)(1-3)).

Concerning drug and alcohol testing and its consequences, the statute further provides that nothing in Title I shall be construed to encourage, prohibit, restrict, or authorize the otherwise lawful exercise by entities subject to the jurisdiction of the Department of Transportation of authority to (1) test employees of such entities in, and applicants for, positions involving safety-sensitive duties for the illegal use of drugs and for on-duty impairment by alcohol; and (2) remove such persons who test positive for illegal use of drugs and on-duty impairment by alcohol pursuant to paragraph (1) from safety-sensitive duties in implementing subsection (c). (Subsection (c) includes the statutory language cited above.) (section 104(e)). These ADA provisions clearly specify that the ADA does not interfere with the compliance by covered employers with DOT regulations concerning drug and alcohol use, including requirements for testing and for removing persons who test positive from safety-sensitive functions. Under the ADA, an employer is not viewed as "discriminating" for following the mandates of DOT drug and alcohol rules.

In considering the effects on the personnel actions that employers choose to take after a safety-sensitive employee tests positive for drugs or alcohol or otherwise violates DOT drug or alcohol rules, it is important to note that the ADA's prohibition of employment discrimination applies only with respect to a "qualified individual with a disability." The ADA specifically provides that an employee or applicant who is currently engaging in the illegal use of drugs is not a "qualified individual with a disability" (section 104(a)). The ADA does not protect such an employee from adverse personnel actions. For purposes of the ADA, the drugs that trigger this provision are those the use, possession or distribution of which is prohibited by the Controlled Substances Act (section 101(6)). The five drugs for which DOT mandates tests fit this definition (alcohol is not a drug covered by the Controlled Substances Act).

What does "currently engaging" in the illegal use of drugs mean? According to the Equal Employment Opportunity Commission (EEOC), whose rules carry out Title I, the term "currently engaging" is not intended to be limited to the use of drugs on the day of, or within a matter of days or weeks of, the employment action in question. Rather, the provision is intended to apply to the

illegal use of drugs that has occurred recently enough to indicate that the individual is actively engaged in such conduct. (56 FR 35745-46, July 26, 1991). It is clear that an individual who has a positive result on a DOT-mandated drug test is currently engaging in the illegal use of drugs. Therefore, under Title I, an employer may discharge or deny employment to an individual who has a positive result on a DOT-mandated drug test.

This provision that an individual who is currently engaging in the illegal use of drugs is not a "qualified individual with a disability" does not apply, of course, if the individual is erroneously regarded as engaging in the illegal use of drugs. In addition, if an individual, even a former user of illegal drugs, is not currently engaging in the illegal use of drugs and (1) has successfully completed a supervised rehabilitation program or otherwise has been successfully rehabilitated, or (2) is participating in a supervised rehabilitation program, the individual can continue to be regarded as a "qualified individual with a disability," if the individual is otherwise entitled to this status (section 104(b)). An employer may seek reasonable assurance that an individual is not currently engaging in the illegal use of drugs (including requiring a drug test) or is in or has completed rehabilitation. Some employers (EEOC uses the example of a law enforcement agency) may also be able to impose a job qualification standard that would exclude someone with a history of drug abuse if it can show that the standard is job-related and consistent with business necessity (56 FR 35746, July 26, 1991).

Unlike the situation with respect to the current use of illegal drugs, the use of alcohol contrary to law, Federal regulation, or employer policy does not deprive an individual of status as a "qualified individual with a disability" that he or she would otherwise have under title I. An individual is protected by title I, however, only if the individual has a disability in the first place. (This is also true with respect to a former drug user or any other individual who seeks the protection of the ADA.) To have a disability, an individual must have a "physical or mental impairment that substantially limits one or more major life activities of such individual, a record of such impairment, or being regarded as having such an impairment" (section 1(2)). While, as the EEOC notes in its title I regulation, "individuals disabled by alcoholism are accorded the same protections accorded other individuals with disabilities" (56 FR 35752, July 26,

1991), not all individuals who use alcohol in violation of law, Federal regulation, or employer policy are "disabled by alcoholism."

The courts interpreting section 504 of the Rehabilitation Act of 1973 (with which ADA employment provisions are intended to be consistent) have concluded that alcoholism can be a disability which may call for reasonable accommodation. See, e.g., *Walker v. Weinberger*, 600 F. Supp. 757 (D.D.C., 1985); *Tinch v. Walters*, 765 F.2d 599 (6th Cir., 1985); *McKelvey v. Walters*, 596 F. Supp. 1317 (D.D.C., 1984); *Anderson v. University of Wisconsin*, 665 F. Supp. 1372 (W.D. Wis., 1987); *aff'd* 841 F.2d 737 (7th Cir., 1988); *Richardson v. Postal Service*, 613 F. Supp. 1213 (D.D.C., 1985); *Sullivan v. City of Pittsburgh*, 811 F.2d 171 (3rd Cir., 1987).

The logic of the ADA, and EEOC's regulatory provisions implementing the statute, suggest that, in determining whether an employee or applicant who has a positive result on a DOT-mandated alcohol test or otherwise violates a DOT alcohol rule is disabled by alcoholism, the employer would answer two questions. First, does the individual have a physical or mental impairment; e.g., is the individual an alcoholic? (People who test positive for alcohol are not necessarily alcoholic.) This question would probably have to be answered with the assistance of a physician or substance abuse professional. Second, if the individual is an alcoholic, does this impairment substantially limit a major life activity or is it (even erroneously) regarded as substantially limiting a major life activity? This question would be answered on a case-by-case basis, following EEOC's guidance (see 56 FR 35740-44, July 26, 1991). Under DOT's alcohol prevention rules, these determinations will be made by or in cooperation with the substance abuse professional that the rules require to be involved following a positive test or rule violation.

The determination of whether an individual is a qualified individual with a disability is made in two steps: (1) Whether the individual has the appropriate education, experience, skills, and licenses, and meets the other prerequisites of the position; and (2) whether the individual can perform the essential functions of the job desired or held with or without reasonable accommodation. Essential functions are the functions that the individual holding the position must be able to perform unaided or with reasonable accommodation. Several factors are considered in determining whether a job

function is essential, including whether the employer actually requires employees in this position to perform the function, whether the position exists to perform the function, whether there are other employees who could perform the function, and whether there is a high degree of expertise or skill required to perform the function.

If the individual is qualified and determined to be disabled by alcoholism, then the employer may not discriminate against the individual on the basis of his or her disability and, if job performance and behavior are not affected by alcoholism, must make "reasonable accommodations" to the individual's known physical or mental limitations, unless the employer can demonstrate that doing so would impose an "undue hardship" on the employer's business.

The selection of an appropriate "reasonable accommodation" is done on a case-by-case basis, as EEOC guidance provides (see 56 FR 35744, July 26, 1991). Reasonable accommodation for an individual disabled by alcoholism could include such actions as referral to an Employee Assistance Program or other rehabilitation program, provision of rehabilitation services, and giving an employee sufficient time to demonstrate that rehabilitation had been successful. See, e.g., *Washington v. Department of the Navy*, 30 M.S.P.R. 323 (1986); *Swafford v. Tennessee Valley Authority*, 18 M.S.P.R. 481 (1983).

Even when an individual is disabled by alcoholism, however, the employer is not required to provide a reasonable accommodation that creates an "undue hardship." Undue hardship involves significant difficulty or expense in, or resulting from, providing an accommodation. EEOC describes an undue hardship as "an accommodation that would be unduly costly, extensive, substantial or disruptive, or that would fundamentally alter the nature or operation of the business." (*Id.*) This concept takes into account the financial resources of the employer (e.g., an accommodation that would be reasonable for a large business may be an undue hardship for a small business). But the concept is not limited to financial difficulty. For example, if a small trucking company determined that the accommodation that one of its drivers needed for an alcoholism-related disability was lengthy in-patient rehabilitation, the company not only might find the accommodation beyond its financial resources but also too disruptive of its operations (i.e., a temporary replacement would have to be hired or the work of the firm be reduced significantly).

Under title I, an employer may hold an employee who engages in the illegal use of drugs or who is an alcoholic to the same qualification standards for employment or job performance or behavior as it holds other employees, even if any unsatisfactory performance or behavior is related to the drug use or alcoholism of the employee (Section 104(c)(4)). For example, if, as the result of alcoholism, an employee is chronically late or absent, or makes frequent job errors, the employee would be subject to personnel action on the same basis as any other employee who exhibited similar behavior for other reasons. (However, if the alcoholic employee were subjected to personnel actions that were not used against non-alcoholic employees who were chronically late or absent, or made frequent job errors, then the alcoholic employee might have a cause of action under the ADA.) The employer is not precluded from accommodating this alcoholic employee, but is not required to do so.

It should also be pointed out that the ADA does not preclude an employer from disciplining or dismissing an employee who commits a violation of the employer's conduct and performance standards, even if the individual is an alcoholic or has another disability. For example, a violation of a DOT operating administration's alcohol misuse rules (e.g., a test demonstrating a prohibited alcohol concentration) could be a violation of the employer's performance and conduct rules, for which the employer's policy could call for the employee's dismissal. This result would not violate the ADA.

There are also situations in which meeting qualification standards of DOT safety rules, or having a valid license or certificate from a DOT operating administration, is an essential job qualification. If a truck driver does not meet FHWA qualification standards to obtain a Commercial Driver's License from a State, or if a pilot does not qualify for an FAA medical certificate, that individual is not a "qualified" individual with a disability, even if the reason for the failure to meet DOT qualifications is a condition that an employer might be required to accommodate under the ADA. The legislative history of the ADA specifically recognizes this special status for DOT qualification standards (see Senate Report 101-116 at 27, August 30, 1989).

Another issue that has been raised in context of the relationship between the ADA and alcohol testing concerns whether an alcohol test is a "medical examination." Non-regulatory guidance

issued by the EEOC suggests that "a test to determine an individual's blood alcohol level would be a 'medical examination' and only could be required by an employer in conformity with the ADA." It should be pointed out that this statement does not, on its face, apply to breath testing (or other methods that do not involve blood samples) for alcohol. The EEOC has not determined whether it views breath testing for alcohol as a "medical examination."

The Department of Transportation takes the position that alcohol testing under the program required by these rules is not properly viewed as a required medical examination. It is not the collection of a breath or body fluid sample that makes a test "medical" in nature. The tests in question are solely for the purpose of determining whether an employee has violated a DOT-mandated safety requirement. The tests are not used for any diagnostic or therapeutic purpose. They are not intended to ascertain whether an employee has any medical condition, and they will not be used for such a purpose. Under these circumstances, the policies underlying the ADA provisions on medical examinations do not apply. Because of the uncertainty that may be created by the EEOC guidance, however, it is useful to consider the implications of regarding alcohol tests as "medical examinations." (The Department is working with the EEOC to resolve this uncertainty.)

Even if alcohol tests are considered to be "medical examinations" for ADA purposes, the effects on compliance with DOT-mandated alcohol testing would be minimal. "Medical examinations" are permitted by the ADA if made after a conditional offer of employment. The pre-employment testing approach set forth in the rules clearly fits this model. For this reason as well as for reasons of efficiency, the Department believes that conducting pre-employment testing after an offer of employment, but before the first performance of a safety-sensitive function, has much to recommend it. In addition, EEOC has stated to the Department that, because of the statutory requirement in the Omnibus Transportation Employee Testing Act of 1991 for pre-employment testing, EEOC does not object to pre-offer alcohol testing under the DOT rules mandated by the statute. Other types of testing mandated by these rules, such as reasonable suspicion, post-accident, and random testing, are likewise acceptable under the ADA. (See 29 CFR 1630.15(e), which makes compliance with the requirements of Federal law or

regulation a defense to an allegation of discrimination under Title I of the ADA.) Congress passed the Omnibus Act more than a year after it passed the ADA, and the former statute's specific mandates for various types of testing clearly, as a matter of statutory interpretation, would prevail over any contrary inferences anyone would attempt to draw from the more general provisions of the latter.

A related issue concerns the confidentiality of the records of alcohol tests. To the extent that an alcohol test is regarded as a medical examination, the records of the test would be "treated as a confidential medical record" under the ADA (see Section 102(c)(3)(B) of the ADA). Under this provision, records of a medical examination are required to be kept in a separate medical file. The purpose of any requirement for confidentiality of a medical record is to safeguard the employee's right of privacy with respect to personal medical information. An employee may, of course, waive such a right. (As a general matter, medical confidentiality provisions allow a patient to permit medical information to be provided to third parties.) The DOT rules, by requiring the employee to consent, in writing, to the provision of test records to subsequent employers or third parties, are fully consistent with normal medical confidentiality waiver practices and with the ADA. It would clearly be anomalous to view a medical records confidentiality provision as prohibiting an employee from voluntarily agreeing that a previous employer, or physician, could send a medical record to a current employer or physician.

The Family and Medical Leave Act of 1993

The Family and Medical Leave Act of 1993 (FMLA) provides certain protections for employees with "serious health conditions." These protections include time off for treatment of these conditions and reinstatement in the employee's position or an equivalent position. Under Department of Labor (DOL) regulations implementing FMLA, "treatments for * * * substance abuse are serious health conditions if all conditions of the regulation are met" (29 CFR 825.114(c)). The inclusion of substance abuse treatment under the DOL regulations has raised some concerns about the potential effect of FMLA requirements on DOT drug and alcohol testing requirements.

As is the case with the ADA, the FMLA does not conflict with DOT drug and alcohol rules. FMLA requirements do not prevent an employer from testing employees as required by DOT rules;

nor do they excuse employees from testing requirements or prohibitions on the use of drugs or the misuse of alcohol. They do not interfere with DOT's requirement that an individual who tests positive may not perform safety-sensitive functions again until the conditions established by DOT rules have been met. (We would point out that, just as every employee who tests positive for alcohol or drugs does not necessarily have a "disability" for ADA purposes, such an employee does not necessarily have a "serious health condition" for FMLA purposes.)

DOT drug and alcohol rules do not prescribe what personnel actions, if any, an employer may take with respect to an individual who tests positive. In certain circumstances, Federal law (e.g., the ADA), State law, or labor-management agreements may constrain the discretion that employers would otherwise exercise with respect to such personnel actions. The FMLA may create additional constraints in some situations.

The scope of additional constraints on employer personnel actions stemming from the FMLA is limited. The statute applies only to employers with 50 or more employees. The statute's protections apply only to employees who work for such an employer at least 1250 hours during a 12-month period. DOL's rules establish a number of procedural requirements that employees must meet to avail themselves of the FMLA's protections. DOL also sets some substantive limits on the applicability of FMLA protections to treatment for substance abuse:

Treatment of substance abuse may also be included, such as where a stay in an inpatient treatment facility is required. On the other hand, absence because of the employee's use of the substance, without treatment, does not qualify for leave. It should be pointed out that the inclusion of substance abuse as a "serious health condition" does not prevent an employer from taking employment action against an employee who is unable to perform the essential functions of the job—provided the employer complies with the ADA and does not take action against the employee who has exercised his or her right to take FMLA leave for treatment of that condition. (58 FR 31799; June 4, 1993).

The Department will work with DOL to resolve any questions that arise concerning the relationship of DOT drug and alcohol testing requirements and FMLA requirements.

Overview of the Operating Administrations' Final Rules

Purpose

The OAs covered by the Act and RSPA are establishing alcohol misuse prevention programs designed to help prevent accidents and injuries resulting from the misuse of alcohol by employees who perform safety-sensitive functions in their industries. Generally, the OA rules prohibit any alcohol misuse that could affect performance of a safety-related function, including (1) Use on the job; (2) Use during the four hours (in most cases) before performance of a safety-sensitive function; (3) Having prohibited concentrations of alcohol in the system while performing safety-sensitive functions; (4) Use during the 8 hours following an accident if the employee's involvement has not been discounted as a contributing factor in the accident or until the employee tests below 0.02; and (5) Refusal to take a required alcohol test. The rules require pre-employment (except for RSPA), reasonable suspicion, random (except for RSPA), post-accident, return-to-duty and follow-up testing for alcohol. The rules also establish a performance standard for adjusting the initial 25 percent random alcohol testing rate for each transportation industry (except for RSPA). Published elsewhere in today's **Federal Register** is a proposal to establish a somewhat different performance standard for adjusting the random drug testing rate for each transportation industry.

The part 40 procedural final rule published elsewhere in this **Federal Register** provides for two tests to ensure accuracy: A screening and a confirmation test. It provides more flexibility to use different testing technologies for screening tests than we had proposed. However, until additional devices can be evaluated and approved as meeting DOT precision and accuracy criteria and procedures for their use are established, the screening tests must be conducted using breath testing devices on the NHTSA CPL, which includes devices with and without printers. Evidential breath testing devices that provide printed results and sequential numbering of tests must be used for confirmation tests. We are separately proposing to permit blood testing in reasonable cause and post-accident situations where an EBT is not readily available. The primary purpose of the testing provisions is to deter and detect misuse of alcohol.

Following a finding that an employee has misused alcohol, as determined

through testing or other means, the rules generally require the employee's removal from safety-related functions and provide a bifurcated system of consequences:

(1) Following a determination that the employee has violated prohibitions in these rules, the employer must remove the employee from and cannot return the employee to a safety-sensitive function until, at a minimum,

(a) The employee undergoes evaluation, and where necessary, treatment,

(b) A substance abuse professional determines that the employee has successfully complied with any recommended course of treatment, and

(c) The employee tests at less than 0.02 on a return-to-duty test.

(2) An employee with an alcohol concentration of 0.02 or greater but less than 0.04 is not permitted to perform safety-sensitive functions for

(a) A minimum of eight hours (except FHWA), or

(b) Until a retest shows that the employee's alcohol concentration has dropped below 0.02.

The rules also impose reporting and recordkeeping requirements and provide for alcohol misuse information for employees, supervisor training, and referral of employees to a substance abuse professional (SAP) for evaluation.

There are some differences among the OA final rules. For example, some OAs have regulatory authority over employers/companies only; others have regulatory authority over employees. Also, employees holding a license or certificate may be subject to agency action against their license or certificate under other rules in addition to the consequences established for violations of these rules. See the individual OA rule preambles for an explanation of any differences from the general requirements discussed above.

Applicability

The existing OA drug rules generally cover persons who perform safety-sensitive functions in commercial transportation. Initially, they affected approximately 4 million persons and include, for example, commercial truck/bus drivers, pilots, pipeline employees, licensed and documented mariners and others serving on board a vessel with a licensed operator, and railroad workers subject to the Hours of Service Act. An FTA final rule published elsewhere in today's *Federal Register* adds drug testing for such workers as transit bus and subway operators. In accordance with the mandates of the Act, the FHWA rule adopting the alcohol

preamble extends their coverage as well as the coverage of the existing FHWA drug rules to persons required to obtain a CDL, including intrastate truck and motor coach operators. This includes drivers and employers not currently covered by the Federal Motor Carrier Safety Regulations (FMCSRs) such as: Federal, State and local government agencies, and church and civic organizations. As a result, the total number of persons covered by the alcohol and drug testing rules has increased to over 7 million. (Maritime industry personnel are covered by the drug rules, but not by these alcohol rules (other than certain ferry boat personnel), although USCG does have some alcohol testing requirements and intoxication standards already in effect.)

In the common preamble to the NPRMs, we asked whether there is any rationale for covering a different population for alcohol testing than drug testing; no one provided such a rationale. The same employees who would cause safety problems if they are using illegal drugs would cause problems if they misuse alcohol. Consequently, the Department continues to believe that the basis for imposing alcohol misuse prevention requirements should be the performance of safety-sensitive functions. Each OA rule defines "covered employee" with respect to its industry and generally covers the same population under its alcohol prevention program. Numerous commenters addressed the categories included in the OAs' definitions of "covered employee." Please refer to the specific OA preamble for the OA's disposition of those comments. Although the term "security" is used with respect to aviation passenger and baggage screeners, that term is redundant and unnecessary; these persons are performing what the FAA defines as safety-sensitive functions—maintaining aircraft security—as opposed to simply having a security clearance (which results in coverage of many Federal employees under government drug testing programs).

The OA rules focus on function rather than a defined job or position. An individual's job may encompass several different functions, some of which are not safety-sensitive. Since alcohol is a legal substance, alcohol use is relevant only to the extent it affects performance of a safety-related function. As a safety regulatory matter, for example, we are not concerned if an aircraft mechanic has a drink before or while performing functions that are not safety-related (as long as no other rule is violated); if the mechanic is receiving all-day training on retirement planning along with non-

safety employees and the other employees can have a drink at lunch, the mechanic may also.

Alcohol Testing Procedures

Each of the OA final rules requires employers to ensure that all alcohol testing conducted under these rules complies with the procedures for alcohol testing contained in the amended 49 CFR part 40 entitled "Procedures for Transportation Workplace Drug and Alcohol Testing" issued by DOT elsewhere in today's *Federal Register*. Each OA final rule incorporates the new 49 CFR part 40 by reference. Since all of those OAs publishing final rules today require alcohol testing conducted by their covered employers to comply with the part 40 testing procedures, the DOT is issuing these procedures separately in order to avoid their unnecessary duplication in each OA rule.

Part 40 requires both screening and confirmation tests for alcohol. The rules require that screening tests with a result of 0.02 alcohol concentration or greater be confirmed by an EBT listed on the NHTSA CPL, which also is capable of printing out each test result and air blank (test of ambient air), and sequentially numbering each test. This provides an immediate confirmed result, which enables immediate removal of the employee who has misused alcohol and also provides a printed record of the result that will prevent disputes about the accuracy and integrity of the testing process. EBTs are reliable and highly accurate at detecting low alcohol concentrations and their use is possible in all transportation settings envisioned in those industries for which the OAs are issuing rules today.

Breath testing devices have been in use a long time; all States accept evidential breath test device results as credible evidence of an individual's violation of a law establishing a *per se* prohibited blood alcohol concentration, so long as the devices are properly calibrated and operated by trained personnel. Each device on the NHTSA CPL, with or without printed results, has been accepted by at least one State for use in court proceedings in that State. (Acceptance by a State of a particular device is not, however, necessary for the use of that device in that State for purposes of the DOT testing program.) In addition, part 40 establishes training requirements for breath alcohol technicians (BATs), maintenance and calibration requirements in a quality assurance plan for EBTs, and additional testing

procedures to protect the integrity of the process.

In response to the comments received, the Department believes that greater flexibility to use different testing technologies would benefit employers, especially for testing in remote locations and tests for which employers do not control the timing or "triggering" event—reasonable suspicion and post-accident. At the same time, the Department believes that any devices used in the testing program must meet the precision and accuracy criteria established by part 40 that the Department has determined are necessary to the integrity and success of these programs and to ensure protection for employees. Only EBTs on the CPL, including those without printers, currently meet these criteria; those without printers can be used for screening tests but part 40 requires that a logbook be kept with each such device to provide a crosscheck for the occurrence of a test and its result.

In addition to the changes concerning EBTs without printers, part 40 will, in the near future, provide more flexibility to use different testing technologies for screening tests than we proposed in the OA NPRMs. NHTSA will develop model specifications (using precision and accuracy criteria), evaluate additional screening devices against them and periodically publish a conforming products list of those additional screening devices (not exclusively breath testing devices) that meet the model specifications. We expect that publication of the model specifications will encourage manufacturers to develop products that meet them. NHTSA will approve those devices that meet its criteria for use in our alcohol testing programs. Please note that the Department also will have to undertake separate rulemaking proceedings to establish procedures for the use of any devices after they are approved. The proposed NHTSA model specifications are published elsewhere in today's *Federal Register*. NHTSA expects to begin evaluation of screening devices after the final model specifications are published. The device manufacturers also would have to certify that they meet existing Food and Drug Administration (FDA) good manufacturing practices and labeling requirements. The timing for the NHTSA approval of screening devices will depend on the volume of devices submitted for approval. The Department is continuing to coordinate with the FDA and other appropriate agencies to determine if additional product evaluations for alcohol screening devices will be necessary.

We also are considering requiring blood alcohol testing in those reasonable cause and post-accident situations where an EBT is not readily available. It would provide increased flexibility to employers to use blood testing where an EBT is available, but would be difficult or expensive to transport to the test site. One benefit of requiring blood alcohol testing in these limited situations is that employers would not have to make EBTs available in as many locations as otherwise would have been necessary. This would also mean that an employer must conduct a blood test where a test would otherwise not occur because an EBT is unavailable. The blood alcohol testing proposal, including blood alcohol testing procedures, is addressed in a separate NPRM published elsewhere in today's *Federal Register*. Before we issue a blood alcohol testing final rule, we need to resolve specimen collection issues and determine how to identify those laboratories that we can rely on to test blood samples accurately. The NPRM also seeks comment on other issues, such as safeguards for employees and procedures for shipping and documentation of blood samples.

Please refer to the part 40 preamble for discussion of other testing methods that are not appropriate for use in these programs at this time, such as urine, saliva, or non-alcohol-specific devices for "performance" or "fitness-for-duty" testing. The flexibility provided by part 40 will enable reconsideration of alcohol-specific testing devices for future use if the device or method meets our precision and accuracy standards and other requirements.

Definitions

Some of the definitions, such as those defining *accident*, *covered employee*, and *safety-sensitive function*, among others, will be different in each OA final rule based on differences in the individual regulated industries. Other definitions, such as *alcohol*, are identical in all of the OA final rules. In response to comments, we have changed the definition of *alcohol* to include other low molecular weight alcohols, such as methyl and isopropyl alcohols that could be used as intoxicants, in addition to ethyl alcohol. This will avoid arguments that a positive reading on a testing device could reflect the presence of other non-prohibited alcohols. They also should be prohibited since they have the same adverse effect. *Alcohol concentration* in all of the rules means the alcohol in a volume of breath expressed in terms of grams of alcohol per 210 liters of breath as indicated by an evidential breath test

under these rules. For example, a breath alcohol concentration of 0.04 means 0.04 grams (four one-hundredths of one gram) of alcohol in 210 liters of expired deep lung air. This breath standard is analogous to a blood alcohol concentration of 0.04.

The definition of *alcohol use* means consumption of any beverage, mixture, or preparation, including any medication, containing alcohol. Some commenters suggested an exception for medication if the employee notifies the employer and the employee's alcohol concentration never reaches 0.02; others strongly opposed such an exception. (See FAA preamble to its alcohol prevention rule for discussion of this issue in the context of the more severe consequences for certain aviation employees imposed by the Act.) Alcohol-based drugs could be used to satisfy alcohol needs rather than medical needs, if permitted. Since ingestion of a given amount of alcohol produces the same alcohol concentration in an individual whether the alcohol comes from a mixed drink or cough syrup, the Department is applying the prohibitions in these rules to the use of any substance containing alcohol, such as prescription or over-the-counter medication or liquor-filled chocolates. Allowing an exception for medication would make it very difficult, if not impossible, to enforce the rules. We believe there are now non-alcohol alternatives for all non-prescription medications. In addition, prescription medications containing alcohol may have a greater impairing effect due to the presence of other elements, e.g., antihistamines. We are not aware of prescription medications used (over a long term) that cannot be formulated in an aqueous preparation and that would themselves be safe to use while at work. Therefore, we have decided to prohibit the use of all medications containing alcohol during, and in the four hours prior to (eight hours for FAA), the performance of a safety-sensitive function. Several commenters opposed a prohibition on the possession of medication containing alcohol. We do not impose such a prohibition in these rules. However, some DOT agencies already have existing regulations tailored to their industries that prohibit or impose conditions on the possession of medications containing alcohol while on the job.

The definition of *substance abuse professional* (SAP), as proposed, encompassed licensed physicians, limited to medical doctors and doctors of osteopathy; as well as licensed or certified psychologists, social workers and employee assistance professionals;

we had asked commenters who else should be included. In response to comments, we have included alcohol and drug abuse counselors certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission (NAADAC), a national organization that imposes qualification standards that we believe are necessary to perform a SAP's functions. We rejected suggestions that the definition include State-certified counselors, because the standards vary dramatically by State; in some States, certified counselors do not have what we consider the necessary experience and/or training. All of the categories listed in the definition must have knowledge of and clinical experience in the diagnosis and treatment of alcohol-related disorders in order to become a SAP.

We have added a definition of *violation rate*, which each OA will use in annually determining whether covered employees in a particular industry meet the performance standard for adjusting the random alcohol testing rate for that industry. The violation rate represents the total of the number of covered employees as reported in OA MIS data annually found during required random tests to have an alcohol concentration of .04 or greater plus the number of employees who refuse a random alcohol test, divided by the total of the number of employees in the industry given random alcohol tests plus the number of those who refused a random alcohol test.

Preemption of State and Local Laws

The Act contains an express preemption of State and local requirements that are inconsistent with the Federal alcohol rules applicable to the aviation, highway, and transit industries. Through its implementation of the Hazardous Materials Transportation Act (HMTA), the Department has long interpreted statutory preemption under an inconsistency standard by using a two-pronged test. The test was derived from Supreme Court decisions on preemption under the Constitution, has been followed successfully by the Department, and has been upheld by court decisions on preemption under the HMTA. In 1990, at the request of the Department, Congress recognized this long-standing interpretation by incorporating it into the statutory preemption provision of the HMTA. (49 U.S.C. App. 1804) The final rules adopt this interpretation of the inconsistency standard for preemption by incorporating the two-pronged test.

Generally, the OA rules preempt any State or local requirement if it is not possible to comply with both the Federal and the State or the local requirements, or if compliance with the State or the local requirement will frustrate the Federal requirement. For example, a State requirement prohibiting the alcohol testing of transit employees is preempted. Also a local requirement for a blood test (outside the limited exception proposed elsewhere in today's *Federal Register*—assuming the proposal will be adopted) to confirm alcohol use by a commercial truck driver is preempted since it will frustrate accomplishment of the Federal rule by adding additional complicated procedures that may make it difficult to fully and accurately comply with the DOT procedures and by adding costs that may make compliance impossible for many companies. The rules do not preempt provisions of State criminal law that impose sanctions for reckless conduct leading to actual loss of life, injury, or damage to property, whether the rule applies specifically to transportation employees or employers or to the general public. One commenter asked whether a State could adopt and enforce the same alcohol prevention requirements as those we establish here. Since the same rules would not burden or conflict with the Federal program, a State would be free to do so.

The purpose of preemption is to avoid the confusion and expense of inconsistent requirements for employers or testing entities that operate in several States and to prevent interference with the functioning of the Federal program by extraneous, burdensome requirements that may defeat its purpose and benefits by making effective implementation difficult or impossible (e.g., by requiring that employers pay for any rehabilitation or requiring confirmation tests beyond those required by DOT). Because of the nationwide application of the Federal program and the interstate nature of the operations covered, even minor requirements in the aggregate may become unduly burdensome. For this reason, we intend to scrutinize closely State and local requirements under this preemption authority. Comments on preemption are specifically addressed in the OA preambles.

Other Requirements Imposed by Employers

Some employers commented that they want to be free to impose stricter requirements on their workforce. Except as provided in the OA rules, employers retain their existing authority with respect to alcohol testing and

termination or rehabilitation of their employees and employees retain their rights with respect to the use or possession of alcohol. An employer may continue to conduct alcohol testing under his/her own authority in addition to meeting the requirements of these rules and provide or support alcohol rehabilitation programs. Employees are free to consume alcohol on their own time so long as that consumption does not violate any of the provisions of these rules or other applicable rules. Some commenters asked us to preserve their right to collectively bargain certain testing requirements. The rules contemplate that many aspects of the employer/employee relationship with respect to these programs will be subject to collective bargaining. For example, who pays for assessment and evaluation is one area we explicitly do not regulate. However, employers and employees are not free to bargain away any of the requirements of these rules. Whatever rights they may have to bargain collectively or otherwise agree on employer-employee relations, they cannot change or ignore Federal safety standards.

Requirement for Notice

Before performing an alcohol test under these rules, the employer must notify the employee being tested that the alcohol test being administered is required by these rules. The notice can be oral, written or as specifically provided in an OA regulation. An employer shall not falsely represent that a test administered under other authority is being administered under Federal rules. The few comments that we received on this issue were evenly divided between those that supported the requirement and those that opposed it. Generally, we think the required alcohol testing form is sufficient to constitute adequate notice.

Starting Date for Alcohol Testing Programs

Most commenters seemed satisfied with the proposed implementation schedule. Several larger employers requested additional time to develop their programs, enter into service provider contracts and to complete collective bargaining; some large employers believed that it would be fairer if all employers had to implement their programs in one year. The attached OA final rules establish the specific implementation schedules for each industry. The schedules are similar to those proposed in the NPRMs and those used in the DOT drug testing rules.

Generally, large employers will have the better part of one year from the

effective date of the final rules in which to implement the requirements and small employers have nearly two years. To accommodate the annual reporting requirements, large employers must implement these programs on January 1, 1995 and small employers must implement these programs on January 1, 1996. Each OA final rule defines employer size and notes variations justified by industry differences; FAA and FRA have a three tier phase-in for covered employers and contractors. The timetables generally allow smaller employers to join alcohol misuse programs already established by larger employers or consortia, which should reduce their costs. Consideration and appropriate mitigation of the rules' impacts on smaller employers is required by the Regulatory Flexibility Act and Executive Order 12866, "Regulatory Planning and Review." We believe it appropriate for small employers to have more time since their size alone may make it more difficult to implement an alcohol misuse prevention program within one year (lack of expertise, resources, etc.). Our experience in the drug testing area shows that these implementation schedules provide sufficient time for larger employers to establish their programs.

All employers must have an alcohol misuse program in place January 1, 1996. Thus, employers that begin to operate after the effective date of these rules must have their programs in place by the deadline according to size or by the time they initiate their operation, whichever is later. These timetables also take into account the time needed by the manufacturers to produce the required modifications to breath test devices or to develop alternative devices. In addition, they will allow time to develop conforming products lists (CPLs) for other screening devices and to complete the blood alcohol testing rulemaking.

Prohibitions

The OAs are establishing the following combination of prohibitions designed to prevent any adverse alcohol effect on a covered employee during performance of safety-sensitive functions.

Alcohol Concentration

Unlike some other drugs, alcohol is a legal substance with legally and socially acceptable uses for persons 21 years of age and older. The Department already has some prohibitions on alcohol misuse. Those OAs that traditionally have regulated employee safety-related conduct in commercial transportation (FAA, FHWA, FRA and USCG) have

selected a 0.04 alcohol concentration as the *per se* standard for determining whether an individual is under the influence of alcohol, and prohibit any use of alcohol on the job. Some OA's (FAA, FHWA and USCG) subject certain persons to pre-duty abstinence periods. FHWA rules require that commercial vehicle operators with any measurable amount or detectable presence of alcohol be placed out-of-service for a 24-hour period. Until adoption of these rules, RSPA and FTA did not have alcohol concentration prohibitions, primarily because neither directly regulates employees.

Today's final rules prohibit covered employees from reporting for duty or remaining on duty requiring the performance of safety-sensitive functions while having an alcohol concentration of 0.04 or greater. It is not possible to relate a given alcohol concentration definitively to impairment in specific individuals. However, as noted earlier, the presence of any alcohol can have an adverse effect on an individual. As a result, the rules define alcohol concentration in terms of breath testing measurement and specifically relate a violation of this prohibition to the alcohol concentration as indicated on the breath testing device. In addition, no employer who actually knows that an employee has that concentration can permit the employee to perform or continue to perform safety-sensitive functions.

Commenters addressing the proposed breath alcohol concentration standard generally supported one of three choices: a 0.04 alcohol concentration standard that triggers the full sanctions of the rule with no consequences attached to lower levels; a similar 0.02 standard; or the proposed 0.02/0.04 standard with its bifurcated consequences.

Most commenters supported a 0.04 alcohol concentration standard. These commenters noted that this standard has been in place in aviation, maritime, and railroad regulations for a number of years, and is the standard that the States are required to adopt for commercial motor vehicle drivers. Many commenters also noted that the evidence of impairment below 0.04 was equivocal, with as many or more studies finding no impairment below that concentration as those that identified some impairment. Commenters further stated that the bifurcated system would be difficult to implement and hard for employees to understand. Finally, both labor organizations and employers stated that a likely consequence of a test result between 0.02 and 0.039 would be termination of employment under

company authority. Labor organizations stated that this consequence would be unfair and that, if the final rules imposed a standard lower than 0.04, employers should be prohibited from terminating employees based on such a result.

We agree with commenters that an alcohol concentration of 0.04 represents the point at or above which impairment for most individuals rises dramatically, thus justifying its use as the standard for commercial transportation employees and for imposing full sanctions under the rules issued today. However, adoption of a "bright line" 0.04 alcohol concentration standard, while consistent with current regulations, does not address what to do with an employee who tests below 0.04.

The existing rules that impose a 0.04 standard generally do not require testing unless there is a triggering event, so the problem of what to do with lower alcohol concentrations is not faced. In addition, when individuals exceed the standard, action is generally taken against a license or some other significant sanction is imposed. Under the rules the OAs are issuing today, we face the problem of whether a person who tests below 0.04 should be permitted to continue performing safety-sensitive functions. Studies about the effects of any alcohol raise our concern about the effects of lower alcohol concentrations on transportation employees. For example, the National Academy of Sciences (NAS) noted that several credible studies measuring task performance at low blood alcohol concentrations indicate that, "[a]lthough individual reactions to alcohol vary depending on * * * [various] factors * * *, sensory and cognitive performance is significantly reduced at or below 0.04 percent BAC." (Zero Alcohol, 1987) The study concluded that "across broad populations of drivers, BACs exceeding about 0.04 to 0.05 clearly increase the probability of causing a crash. * * * [W]hen the driver's age and experience with alcohol are controlled for statistically, the risk of crash involvement increases at any recorded BAC above zero."

A recent NHTSA report to Congress stated that "[a]lthough the effects of alcohol on impairment and crash risk appear more dramatically above 0.05 or 0.08, for some drivers, any measurable alcohol puts them at increased risk." (Alcohol Limits, 1991) It noted that relatively few studies have looked at alcohol concentrations below 0.04; therefore, only a small number of studies have found clearly impairing effects for alcohol concentrations below 0.04 (commenters noted this as well).

NHTSA noted that individuals performing more complex tasks (especially those involving a subsidiary task requiring time-sharing or divided attention) often show evidence of impairment at alcohol concentrations as low as 0.02. NHTSA concluded that one cannot specify an alcohol concentration above which all drivers are dangerous and below which they are safe or at "normal" risk.

The Transportation Research Board, in a study performed for the FHWA during its Commercial Driver's License rulemaking, recommended a 0.04 BAC as the concentration where the serious penalties should apply to commercial motor vehicle drivers, but it noted that some degree of impairment such as slowed reaction time, loss of coordination, and deterioration in judgment begins with any BAC above zero. (Zero Alcohol, 1987) FHWA, in fact, adopted this recommendation in promulgating its existing rules, from which we derived the bifurcated alcohol concentration standard proposed in the NPRMs. The FHWA rule imposes full sanctions for alcohol tests results of 0.04 and over. It requires removal of the employee from service for 24 hours for any alcohol test result between 0.00 and 0.04. Commercial motor vehicle operators engaged in interstate commerce have understood and complied with this bifurcated standard for several years, so other transportation industry employees should not have trouble understanding the standard. We do not believe that it is necessary to adopt a "bright line" 0.02 or 0.04 alcohol concentration standard to avoid confusion.

Commenters who supported a 0.02 standard generally favored a "zero tolerance" policy, and believed that the rules should set the standard at the lowest level of accurate detection. Many of these commenters stated that any person who would use alcohol sufficiently close in time to the performance of safety-sensitive duties to have any measurable alcohol concentration was acting in a manner contrary to safety and should be appropriately sanctioned. Additionally, like those commenters supporting a 0.04 standard, many commenters believed that a single standard would be easier to implement, understand, and enforce. We believe that the imposition of the relatively severe rule sanctions at the 0.02 "bright line" alcohol concentration proposed by some commenters is not justified. Although the available studies support removing the employee from safety-sensitive functions, the level of impairment or adverse effect does not warrant the additional actions required

for concentrations of 0.04 and above. Employers will likely review employee test results between 0.02 and 0.04 on a case-by-case basis to determine any appropriate action under their own authority.

A few commenters supported one of two other positions: absolute zero tolerance, with anything over 0.00 resulting in a rule violation, or a standard similar to those used by the States for driving while intoxicated (0.08 or 0.10). They presented the former position as being most consistent with safety. The NAS and the National Transportation Safety Board (NTSB) have favored setting an explicit policy of zero BAC. The NTSB said that "[i]t should be absolutely clear that no alcohol is acceptable in commercial transportation because research has demonstrated that low blood alcohol levels can produce impairment." Its comments on these rules reiterate this position. As several commenters who favored an 0.02 standard noted, adoption of an absolute zero standard is not possible, as discussed below, because of the current limits on testing technology. Commenters supporting the latter standard based on State law believed that it would sufficiently protect safety without unnecessarily infringing on employees' rights. Adoption of either the 0.08 or 0.10 standard would be a step back from the current requirements imposed on commercial operators. In light of the studies referred to above, it also would be inconsistent with ensuring public safety.

Those commenters who favored the proposed bifurcated system believed it would provide employers with the greatest flexibility in ensuring that alcohol use at very low levels did not adversely affect safety while not requiring the more significant costs (evaluation, replacement, etc.) or stigma associated with a rule violation. These commenters did not believe that the provision would be difficult to understand or enforce. We agree with them.

Having any standard other than 0.00 raises troubling questions about whether an employer should allow an employee whose test shows an alcohol concentration between 0.00 and 0.04 to continue performing a safety-sensitive function. Clearly, the Department's concern about public safety and an employer's additional concern about liability are raised in a situation in which an employee "passed" a test with an indicated alcohol concentration below 0.04 and then begins or resumes performing safety-sensitive functions. The likelihood of being involved in an

accident when performing safety-sensitive functions with a measurable alcohol concentration is increased. Therefore, we are adopting the 0.02-0.04 standard, as proposed, with the two-tiered system of consequences. The covered employee must be removed from a safety-sensitive position at any alcohol concentration of 0.02 or greater. If the employee's alcohol concentration is 0.02 or greater but less than 0.04, the employee will not be allowed to perform safety-sensitive functions until (1) the next scheduled duty period (usually the next day), if at least eight hours has elapsed (24 hours for those regulated by FHWA), or (2) a retest shows the alcohol concentration has fallen below 0.02. If the employee has an alcohol concentration of 0.04 or greater, the employee cannot return to a safety-sensitive function until (1) evaluated, (2) treated, if required by a SAP, and (3) retested with a result below 0.02. In either case, the employee will be prevented from posing any danger to the public. An employer can take more serious action for the presence of alcohol at any concentration if it has authority to do so independent of DOT regulations.

The Department has used the 0.02 alcohol concentration as the lower standard rather than 0.00, because it represents the lowest level at which a scientifically accurate alcohol concentration can be measured given the limitations of any current technology (e.g., blood, breath). Results below 0.02 cannot be verified as indicating consumption of alcohol (could represent natural ketosis) and would be forensically insufficient to support consequences under these rules. We cannot be sure if such results indicate if the employee really has any alcohol in his or her system. In essence, use of a 0.02 standard represents a zero tolerance standard for alcohol.

Some commenters raised questions about relying on the NHTSA CPL for testing devices that must measure as low as 0.02. NHTSA's model specifications for devices on the CPL were developed for police use under criminal laws prohibiting alcohol concentrations of 0.10 and above. Although all of the EBTs on the CPL exceed existing requirements, on September 17, 1993, NHTSA published a notice modifying the model specifications for evidential breath testing devices to be consistent with the requirements of these rules and updating the list of conforming products (58 FR 48705). The new specifications establish evaluations for precision and accuracy of devices at the 0.0, 0.02, 0.04, 0.08 and 0.16 alcohol

concentrations. When the OAs proposed the rules being issued in final today, we were aware that NHTSA was going to take this action to respond to the ongoing efforts of States to lower prohibited alcohol concentrations to 0.08 in general and to 0.02 for drivers under 21 and to the prohibition on 0.04 alcohol concentration or greater for commercial drivers.

On-duty Use

The rules also prohibit a covered employee from using alcohol while performing safety-related functions and prohibit an employer who actually knows of such use from allowing the employee to perform or continue to perform safety-sensitive functions. The need for this prohibition is self-evident. Some commenters suggested an exception for medication if the employee notifies the employer and the employee's alcohol concentration never reaches 0.02; others strongly opposed such an exception. As discussed above under the discussion on the definition of alcohol use, we have decided not to allow a medication exception in these rules.

Pre-duty Use

Commenters had a mixed reaction to the pre-duty use prohibition. Several opposed it as unnecessary due to the on-duty prohibition, intrusive on an employee's private life (and legitimate use of a legal substance), unfair to "on-call" employees and unenforceable. Others supported the prohibition, but several of them wanted it extended from the proposed four hours to a range of five to 12 hours; eight hours proved to be the most popular and the choice of the NTSB for all OAs. One commenter wanted a clearer definition of what actual knowledge means. Some commenters wanted a medication exception for pre-duty use.

Drinking during off-duty periods may impinge upon a person's ability to function safely on the job. Although the alcohol was consumed during the employee's private or off-duty time, it may still be in the employee's system when he or she reports for work. We do not and cannot effectively require the testing of all employees when they report to work, so the existence of testing is not in itself sufficient. Setting a pre-duty abstinence period also provides clear instructions to an employee who might not otherwise appreciate or understand that drinking before coming to work could result in a positive test. Therefore, we believe that we need to retain a pre-duty abstinence period in addition to the on-duty prohibition to avoid the possibility of

adverse effects from alcohol in the system due to pre-duty ingestion.

The OA rules generally prohibit a covered employee from using alcohol within the four hours preceding the performance of safety-sensitive functions. Four hours is sufficient to ensure that an employee is alcohol-free in most situations, without unduly intruding upon the employee's private life; a longer period would be more intrusive. The rules also prohibit an employer, who actually knows that the employee has used alcohol within that period of time, from allowing the employee to perform or continue to perform safety-sensitive functions. An employer cannot always be aware of an employee's pre-duty behavior, but actual knowledge can come from the employer's direct observation of the employee, a reliable witness or the employee's admission of alcohol use. Generally, this prohibition is enforceable vis-a-vis the employer only in "actual knowledge" situations.

The FAA's long-standing eight-hour pre-duty use prohibition for crewmembers will remain in effect. The applicability of the four-hour prohibition to "on-call" employees varies by industry. Please refer to the specific OA rules on this issue. Because duty tours often are not predictable in the rail industry, the four-hour period is shortened for unscheduled assignments to the interval between being "called to duty" and "reporting for duty." RSPA's rule provides an emergency exception to the prohibition on pre-duty use. For example, the only qualified employee in the area, who has used alcohol within the previous four hours, can be called to respond to an emergency call to perform the simple act of turning the valve to shut down a ruptured pipeline. The rule prohibits alcohol use after the employee has been notified to report for emergency duty. The exception does not support the employee's continued performance of the safety-sensitive functions once safety is achieved or if a replacement employee is readily available. As discussed above under the discussion on the definition of alcohol use, we have decided not to allow a medication exception in these rules.

Use Following an Accident

Most commenters had problems with this prohibition, although many supported the concept. Several noted that it would be unenforceable because the employer often does not have control over the employee and is unnecessary where the employee is in "on-duty" status, since the on-duty prohibition applies. Numerous commenters pointed out that the

prohibition is too difficult to apply to employees who do not know about the accident or to mechanics who may have worked on the vehicle involved in the accident. Those comments on mechanics are specifically addressed in the OA preambles.

Since it is important to determine whether alcohol is implicated in an accident, a covered employee who has actual knowledge of an accident in which his or her performance of a safety-sensitive function has not been discounted by the employer as a contributing factor to the accident is prohibited from using alcohol for eight hours following the accident. The prohibition ends eight hours after the accident (when a test is no longer required), once the covered employee has taken a post-accident test under these rules, or once the employer has determined that the employee's performance could not have contributed to the accident.

While we recognize that there are some situations where it may be difficult to enforce, the prohibition is important. The Department is aware of accidents in which employees, who should have been tested, left the scene and then, when they were brought in for testing, alleged that they consumed alcohol after the accident. This rule prevents employees who know they are subject to testing from explaining "positive" findings on an alcohol test by alleging they had a drink after the accident, since such action also constitutes a rule violation. It also is useful for employees who may not know whether or not they remain in "on-duty" status after an accident to be aware of this prohibition. We are imposing an "actual knowledge" requirement, because, in some situations, the employee involved in an accident may not know of the accident. For example, a mechanic makes a mistake that causes an accident a couple of hours later or half a continent away. If the mechanic is unaware of the accident, we agree with those commenters that do not believe a ban on drinking can be effectively enforced. However, if it is established that the mechanic did know of the accident and his or her potential involvement (e.g., was told by a supervisor) and performance of the safety-sensitive function was not too removed in time to make conducting a test futile, the mechanic would be prohibited from drinking. See the specific OA rules that limit the application of this prohibition to performance of a safety-sensitive function at or near the time of the accident or on the vehicle or aircraft involved. Also, the FRA rule does not

include this requirement because under current FRA rules the employees involved remain in on-duty status after an accident.

Refusal to Submit to a Required Alcohol Test

The rules prohibit a covered employee from refusing to submit to required post-accident, random, reasonable suspicion or follow-up alcohol tests. The RSPA rule provision applies only to those types of tests it requires. This, in effect, provides that the employee must take those tests when required. The consequences for a refusal to submit to a required test are the same as if the employee had tested at 0.04 or greater or had violated any of the other prohibitions in these rules. Failure to provide adequate breath for testing when required without a valid medical explanation, engaging in conduct that clearly obstructs the testing process, or failure to sign the alcohol testing form (if the employee did not take test) constitute a refusal to submit to testing. For further discussion of these points, see the preamble to part 40. A covered employee subject to a post-accident test who leaves the scene of the accident before being tested (except, for example, when necessary to receive medical treatment) and is not reasonably available for a test is deemed to have refused to submit to a required test. A refusal also can occur where an employee, who screens positive for alcohol, decides to admit alcohol misuse in violation of the rules and refuses the confirmation test. This situation is different from allowing employees to voluntarily "mark off" from duty when not threatened with a test under these rules, if they feel that they are unable to perform their jobs due to alcohol misuse. The employer must still confirm the positive screen to protect the integrity of the process and to comply with the statutory requirement for a confirmation test. In the absence of the confirmation test result, the employee could later disavow the admission and challenge the screen test result. The rules prohibit an employer from permitting an employee who refuses to submit to testing to perform or continue to perform safety-sensitive functions. In addition, the FRA rule prohibits anyone refusing a required test from engaging in covered service for nine months.

Some commenters, including the NTSB, wanted the penalty for a refusal to test to be removal from safety-sensitive functions for 24 hours. We disagree and intend to apply the full consequences of these rules to an employee's refusal to take required

alcohol tests. Failure to treat a refusal as a positive has two major shortcomings: it eliminates deterrence since those misusing alcohol can simply refuse the test if caught and get only a "minor" penalty; in addition, simply removing them from safety-sensitive duties for 24 hours does not help fix the problem—the employee should be evaluated by a SAP before returning to a safety-sensitive function.

An applicant's or employee's refusal to submit to a pre-employment test or a return-to-duty test does not trigger consequences under the rules that result in the need for evaluation. In those cases, the applicant or employee is not in a safety-sensitive position and does not have to be removed from a safety-sensitive position. Since those tests are a condition precedent to starting or returning to safety-sensitive functions, the applicant or employee simply could not be hired or returned to duty.

Tests Required

General

The Act requires that the industry alcohol misuse prevention programs provide for pre-employment, reasonable suspicion, post-accident and random testing. Periodic tests, which generally are performed as part of required physical examinations for certification of some employees, are discretionary under the Act. The OA rules require the forms of testing mandated by the Act, as well as return-to-duty and follow-up testing; however, the Department has decided not to require periodic testing for alcohol. We agree with the commenter who questioned the value of periodic alcohol testing if the employee knows when the test is to be conducted.

The testing programs are designed for the deterrence and detection of alcohol misuse, which, in turn, promote our compelling interest in ensuring transportation safety. Whether conducted by breath, blood or other method, alcohol testing is considered a Federally-mandated "search", under the Fourth Amendment. Accordingly, we are limiting alcohol testing to the specific time periods surrounding the performance of safety-related functions. That limitation provides the requisite nexus to ensuring proper performance of safety-related functions that is our primary concern and the principal purpose of these rules. The tests required by these rules will be conducted after a triggering event (pre-employment, post-accident, reasonable suspicion, return-to-duty, follow-up) and just before, during or just after performance of a safety-sensitive function (random). The determination

(triggering event) that a reasonable suspicion test is necessary must occur during the time surrounding the performance of a safety-sensitive function. Many commenters raised practical and policy concerns about at least one of the different types of testing. These concerns are specifically addressed below in the discussions relating to each type of testing.

Pre-employment Testing

A substantial number of commenters were concerned about the costs of pre-employment tests and considered them silly "intelligence" tests and a waste of time. The National Airline Commission specifically recommended that "[n]ew pre-employment alcohol testing rules do not need to be adopted * * *". The Act explicitly requires pre-employment testing for covered transportation industry employees, so we do not have the discretion to eliminate it from these programs. We recognize that, as the commenters noted, drinking off duty generally is legal and that alcohol remains in the body for only a short period of time. Often, a test result indicating alcohol use may only indicate bad judgment or bad timing (e.g., one notices an employment advertisement after having beer and a hamburger for lunch, immediately applies, and is tested) instead of alcohol misuse.

To make such a test more meaningful, we are requiring a covered employee to undergo alcohol testing any time prior to the first time the employee performs safety-sensitive functions for an employer. This could occur the first time that the employee performs a safety-sensitive function after being hired or after a transfer within the employer's organization. Some commenters suggested that such tests only be required upon a conditional offer of employment. The rules give the employer the flexibility to test at any time during the hiring process, including before or after the employee receives a conditional offer of employment, or before (preferably just before) the employee starts performing safety-sensitive functions. (Please refer to earlier ADA section for discussion of treatment of alcohol testing as a medical test, which would have to be done after a conditional offer.) The latter choice will enable the employer to avoid the cost of testing several applicants for each job, tie pre-employment tests to the performance of safety-sensitive functions and accommodate the statutory language requiring a pre-employment test for an "employee", rather than an applicant. The former option will permit identification of

someone with alcohol in his/her system before incurring additional hiring expenses. For the above reasons, the definition of "covered employee" used in these rules includes applicants for a safety-sensitive function as well as current employees applying to move into a safety-sensitive function. Many commenters thought that the rules would require every employee to report for work early every day for a regularly scheduled or randomly-conducted pre-duty test. The pre-employment testing requirement does not apply each time the employee reports for safety-sensitive duties, only the first time. Some commenters were confused by the use of term "pre-duty" in "pre-employment/pre-duty" testing and to describe the prohibition on using alcohol during a time period before performing a safety-sensitive function. For that reason, we have changed the name of the test to "pre-employment", but note that it covers both new and transferring employees.

The rules prohibit an employer from allowing an employee to perform safety-sensitive functions unless that employee has been pre-employment tested with a resulting alcohol concentration less than 0.04. If the pre-employment test result indicates an alcohol concentration of 0.02 or greater but less than 0.04, the employee cannot perform or be allowed to perform safety-sensitive functions until the alcohol concentration falls below 0.02 on a subsequent test or until the next scheduled duty period, if it is not less than eight hours following the test. Nothing in the rules prohibits an employer from later retesting an applicant with a positive result. The rules do not confer any rights or consequences upon applicants or employees who have a positive result on a pre-employment test.

Under the rules, an employer may elect not to administer a pre-employment test if the employee has had an alcohol test conducted under any OA alcohol misuse rule following part 40 procedures with a result less than 0.04 within the previous six months and the employer ensures that no prior employer of whom the employer has knowledge has records showing a violation of these rules within the previous six months. Generally, this means that, when checking with a prior employer to verify that the applicant had "passed" a previous alcohol test, the new employer also must verify that the prior employer has no records of a violation of a OA alcohol misuse rule. If the new employer knows the applicant had other employers within the last six months, the new employer must check them too.

This option provides the greatest flexibility for avoiding the constant retesting and related costs involved in an industry, such as trucking, which has a high employee turnover rate. Some commenters did not approve of the requirement to release previous test results to a new employer. We believe that it is important to include this option in these programs; therefore, we do not intend to allow employers to refuse to provide information on a former employee, so long as the request meets the requirements of these rules. Since the information can only be released with the employee/applicant's permission, we do not believe there is a sound basis for the former employer refusing to release the information. An employer, of course, can choose to conduct pre-employment tests in lieu of reviewing information on past employment authorized by the employee and provided by a former employer.

One commenter asked that the proposed exception to pre-employment testing be extended to include negative test results from the previous 12 months, instead of the previous six months. We have decided not to extend the exception period to 12 months; we are trying to provide some flexibility, but beyond 6 months it does not seem to us that it would be a reasonable assumption that the employee continues to be free of alcohol misuse.

In the common preamble to the NPRMs, we asked whether we should require employers to give notice that a pre-employment test will be conducted. We have decided not to impose such a requirement, because it would be too time-consuming and burdensome on the hiring process, particularly in those industries where hiring occurs on the spot. The fairness issue (testing positive after a beer at lunch) is likely to diminish over time as more and more employers conduct these tests and applicants become more aware of their use.

Post-accident Testing

Post-accident alcohol testing already is required by Federal regulation in some transportation modes and is used as a valuable accident investigation and enforcement tool. States also conduct post-accident tests, depending upon the circumstances and their authority to test.

Effective post-accident testing for alcohol at remote locations can be more difficult to accomplish than drug testing, because alcohol passes from the blood and breath more quickly than most drugs. Also, delays in transporting trained personnel and testing equipment

to an accident site can result in negative tests.

The OA rules generally require that as soon as practicable during the 8 hours following an accident, each employer shall test each surviving covered employee for alcohol, if that employee's performance of a safety-sensitive function either contributed to an accident or cannot be discounted as a contributing factor to the accident. The need for testing is presumed; any decision not to administer a test must be based on the employer's determination, using the best information available at the time the determination is made, that the employee's performance could not have contributed to the accident. The definitions of accidents or occurrences that will trigger a post-accident test vary by industry and are discussed in each OA's final rule. They generally are the same as the triggering events for post-accident drug testing. See the OA final rules for modifications to the general approach or for disposition of comments on the events that trigger post-accident testing. For example, under the FTA rule, post-accident testing is mandatory if there is a fatality.

Any employee subject to post-accident testing shall remain readily available for such testing or may be deemed by the employer to have refused to submit to testing; such a refusal is treated as if the employee recorded a test result of 0.04 or greater. Where possible, employers should make every effort under the circumstances surrounding the accident to ensure that the employee, even one who has been permitted to leave—or has had to leave—the site, is available for a post-accident test. This, of course, does not mean that necessary medical treatment for injured people should be delayed or that an employee cannot leave the scene of an accident for the period necessary to obtain assistance in responding to the accident, materials to secure the accident site, or necessary emergency medical care.

A number of commenters believed that conducting a post-accident test within eight hours is unrealistic; they wanted a 32-hour maximum limit as required in most OA drug rules. Because alcohol is eliminated from the body much faster than drugs are, using a 32-hour limit for alcohol testing is inappropriate. We chose an eight-hour maximum time limit for post-accident alcohol tests, because if a test is not administered within eight hours following the accident, there is little likelihood of finding a meaningful alcohol concentration resulting from use preceding the accident. Some commenters, including the NTSB,

wanted the post-accident time limit shortened to two to four hours because no alcohol is likely to be detected after eight hours. Although shorter time limits may result in a more useful test result, they may not be reasonable; they ignore the likelihood that additional time may be needed for those accidents that occur in remote areas or are not discovered right away.

It is important that the employer administer a post-accident test as soon as possible to determine whether there was any alcohol misuse. If a post-accident test is not administered within two hours following the occurrence of the accident, the employer must prepare and maintain on file a record stating why the test was not promptly administered. Some commenters wondered if the time ran from the accident or from the time the site was secured. One commenter suggested that the two hours should begin after the determination that the employee may have caused the accident. Because alcohol metabolizes so rapidly, we disagree that the two hours should run from the determination that an employee may have caused the accident or after the site has been secured; those actions could take several hours.

After eight hours has passed, the employer then shall cease attempts to administer the test and record why the employer was unable to administer a test. Some commenters grumbled about the record requirements. We believe that recording this information is necessary for program oversight and to encourage employers to make the maximum effort to conduct any necessary post-accident tests in a timely manner. The Department recognizes there may be valid reasons for not conducting the tests in these time frames, but every effort must be made to do so. We have tried to ease the reporting burden by dropping the proposed requirement that employers submit these post-accident reports to the appropriate OA. Instead, rules now require only that the employer maintain records on why a post-accident test could not be conducted and make the records available to the appropriate Department officials upon request. It is important to note that this test is not meant to be a full toxicological workup for the purpose of determining accident causation. The primary purpose of the test is to determine whether the employee(s) involved should be removed from safety-sensitive functions.

Most commenters who addressed the issue of who should be required or permitted to perform the post-accident test supported OA acceptance of tests conducted by law enforcement officers,

even if the testing does not comply with part 40 in every respect; a couple of commenters opposed this idea. One commenter pointed out that most States have implied consent laws; once the police test the employee and place him or her in jail (presumably after a positive test), the employer will not have access to the employee during the critical eight hours and must be able to use the police test as a substitute, if made available. Generally, we believe that employers should conduct their own post-accident testing under these rules. However, as commenters have pointed out, the nationwide highway transportation system presents difficult post-accident testing problems. Motor vehicle operators can range far beyond the control of their employers, who may not be informed of the occurrence of an accident for an extended period. We agree that breath or blood alcohol tests conducted by on-site State and local law enforcement or public safety officials should be acceptable in lieu of post-accident testing by FHWA employers in situations where that test can be administered earlier than the employer can get to the scene or when an alcohol test cannot be conducted by the employer within eight hours. These local authorities often are first to arrive at an accident site, particularly if the accident occurs in a remote area, and sometimes are equipped to conduct tests. Such tests must meet State standards that would already make them acceptable in court. Although commenters to other OA rules expressed support of acceptance of such tests in their industries, only the FHWA rule will provide for the exception because the need is most acute for motor vehicle operations. Other OAs, e.g., FAA, have separate rules that would enable them to obtain the results of these tests, if necessary, or face fewer difficulties in finding out about or locating an accident. We recognize that we cannot always ensure cooperation in getting test reports from the police. However, where such results are made available, they would be acceptable under the FHWA program and part 40, provided that breath testing is conducted with an EBT on the CPL and by a law enforcement officer certified on that EBT, and that blood testing is conducted in compliance with State-approved procedures. Please refer to the FHWA preamble for additional discussion.

Numerous commenters believed that post-accident testing is necessary, but that it is unreasonable and impracticable without the option to use other methodologies, such as blood, saliva and urine. As stated earlier, we

are considering permitting the use of post-accident blood testing and the possible use of other devices for screening tests. Until more is done, we cannot ensure the reliability and integrity of other devices. FRA has its own preexisting procedures for conducting a full toxicological analysis following an accident; see the FRA rule for its post-accident testing requirements.

Random Testing

A significant number of commenters opposed random testing, citing its costs and burdens in comparison to the perceived lack of significant problems in their industries. Several viewed training, educational efforts and employee assistance programs as better investments than random testing. Some commenters supported the need for random testing. The Act requires random alcohol testing of safety-sensitive employees in the aviation, rail, motor carrier and transit industries. It is the only type of testing not triggered by or conducted in reaction to another event; its primary objective is deterrence. Although we agree that investment in education and employee assistance efforts will deter some employees from alcohol misuse and contribute to the overall success of the alcohol misuse prevention programs, some employees will only be deterred by the existence of random testing. The additional deterrence provided by random testing is critical to ensuring public safety. Court decisions have indicated that the lack of good data indicating a specific problem in a particular industry is not a bar to our taking action to prevent or address the spread of a societal problem to that industry. Moreover, the lack of data may be due to the fact that currently there is little or no testing. Finally, and most importantly, the Act provides no discretion; we must require random testing. The rule does provide, however, that two consecutive years of very low industry positive random alcohol rates will result in a lowering of the random alcohol testing rate for that industry, thereby reducing employers' costs.

The OA rules (except RSPA) require each employer to randomly select a number of covered employees at various times during each year for unannounced alcohol testing. The number of employees selected must be sufficient to equal an annual rate of not less than 25 percent (initially) of the total number of employees subject to alcohol testing under a particular OA's rules. Thereafter, the industry's random alcohol rate will be adjusted based on a performance standard related to its

random alcohol violation rate. Because of safety concerns, two years of data are necessary to justify lowering the random alcohol testing rate; one year of data is sufficient to raise it. (See more specific random rate discussion below.)

The employer must select covered employees for testing through a scientifically valid method, such as a random number table or a computer-based random number generator that is matched with employees' Social Security numbers, payroll identification numbers, or other comparable identifying numbers. One commenter believed that in-house random selection is discriminatory in practice and employers need to use the services of an outside firm. Each covered employee must have an equal chance of being tested under the random selection process used. A system using random number table or random number generator would not be discriminatory because the employer could not designate particular employees for testing. The dates for administering random tests must be spread reasonably throughout the year (the deterrent effect would disappear if employees know that the employer had completed all required random tests for the year) and should not be predictable (e.g., every Monday or the first week of each month). To achieve this, many employers may find it best to join a consortium. Because of the randomness of the testing, some employees may be tested more than once during the year, while others will not be tested at all.

In the view of some commenters, random testing would provide few safety benefits since it is limited in time to performance of safety-sensitive functions. A few commenters suggested removing those limitations and applying the requirement to all employees at any time. As stated above, we believe that the deterrence provided by random testing will increase safety. To ensure their reasonableness for Constitutional purposes (discussed earlier in this document), the rules provide that an employee can be tested for alcohol only while the employee is performing safety-sensitive functions, just before the employee is to perform safety-sensitive functions, or just after the employee has ceased performing such functions. Obviously, the best time to test is before the employee begins to perform the safety-sensitive function. Detection at that point will prevent the employee from actually performing the function while he or she had alcohol in his or her system. However, if the employee understands that a random test can be administered only before he or she begins work and there is an

opportunity to drink during work, deterrence is limited. The ability to test just before, during or just after performance increases the deterrent effect and may enable detection of employees who use alcohol on the job. Although it may be easier to test at any time, if the test is not tied to safety, we do not believe there would be a sufficient basis under the Constitution to conduct the test.

One commenter wanted a better explanation of "just before, during and just after" performance of safety-sensitive functions. The purpose of the concept of "just before" and "just after" is to avoid the problem that some safety-sensitive functions cannot be interrupted for the performance of a test (e.g., piloting an aircraft). We have not defined the concept in terms of a specific time, but it is intended to be close enough to the actual performance of the safety-sensitive function that the test results will clearly indicate that the employee would be or was at 0.04 or above (or 0.02 or greater but less than 0.04) at the time when performing those functions. To accomplish this, employers should ensure that each covered employee selected for random testing proceeds to the testing site immediately. In the event the employee is performing a safety-sensitive function when notified, the employer must ensure that the employee ceases the function consistent with safety and proceeds to the site as soon as possible. See discussion in the specific OA preambles on what the OAs expect "immediately" to mean in the context of reporting for a random test.

Consortia/Random Testing Pools

To promote efficiency and reduce costs, particularly for smaller employers and employers subject to more than one OA rule, we generally permit the combination of geographically-proximate employees covered by different OA rules into one random testing pool. To maintain fairness and the equal chance of each type of employee for selection, certain conditions apply. For example, employees in any industry who travel most of the time could constitute one pool; others who remain in the vicinity of the testing site would be in another. However, if the testing method chosen required testing of employees immediately upon selection or whenever they arrived at the testing location after their selection (but still unannounced), there would be no need for separate pools. Any acceptable method must ensure that each employee has an equal chance of being selected for testing. Although multi-modal pools

are permitted, they must meet any other specific OA requirements, such as possible differing industry random testing rates.

If the employer joins a consortium, the rules permit the calculation of the annual rate (where the rates are the same) on either the total number of covered employees for each individual employer or the total number of covered employees subject to random testing by the consortium's pool covering the employer. This means that a consortium member could have less than its required number of random tests conducted if the overall consortium rate equals the required rate. Thus, if Employer A has twenty covered employees and the consortium has 500 covered employees in the pool covering Employer A, and a 25 percent rate applies, if Employer A chooses to have the rate based on the consortium, the consortium must conduct at least 125 tests even if none of the covered employees of Employer A are actually tested. So long as each employee has an equal chance of being tested each time the consortium conducts random tests, the requisite deterrence factor exists. Membership in a consortium should improve deterrence for small companies because their employees would continue to perceive an equal chance of being selected throughout the year.

Random Alcohol Rate Performance Standard

In the NPRMs, we requested comment on what annual rate to require for random alcohol testing within a 10 to 50 percent range. Most commenters, particularly employers, wanted a 10 percent random alcohol testing rate beginning the first year; although substantial numbers selected 25 percent or a range between 10 and 25 percent and several wanted to use 50 percent as currently required in the drug testing rules. Many commenters expressed a greater preference for having the same testing rate (and the lower the better) for both drugs and alcohol, because combining the programs would save more money than just lowering the testing rate. They argued that, with drug testing, studies have shown that lowering the testing rate did not affect deterrence. (At least one commenter argued, candidly, that since in its view random alcohol testing is worthless but the Act required it, we should set the lowest random rate possible to reduce employer costs.) According to commenters, lower random alcohol testing rates are appropriate because alcohol use has declined, and many employers have strong employee assistance programs in place, which did

not exist when drug testing was phased in. Finally, most noted that it is easier to detect alcohol misuse through supervisor or co-worker observation. Specific to this rulemaking, the National Airline Commission stated that " * * * any random alcohol testing of airline employees should be at no more than a 10 percent rate."

We note that in July 1991, the FRA initiated a comparative study of random drug testing rates and the impact on deterrence, as measured by the positive rate. The study compared 4 railroads testing at 50 percent (control group) with 4 railroads testing at 25 percent (experimental group). The positive rate for the control group when the study was initiated was 1.1 percent; for the experimental group it was 0.89 percent. In the first year (July 1991 through June 1992), the control group's positive rate was 0.90 percent; the experimental group's was 0.87 percent. For the period July 1992 through June 1993, these groups had positive rates of 0.80 percent and 0.94 percent, respectively. Statistically, the differences in the positive rates between the control and experimental groups are not significant.

Many would argue that the higher the random testing rate, the greater the likelihood of getting "caught" and, therefore the greater the likely deterrence. Detection is also higher at higher rates. However, if the likelihood of detection is small (e.g., because alcohol metabolizes so quickly), testing may result in little deterrence unless very high rates are used. But costs also rise as the number of tests increases. The concern is whether extra deterrence is worth the extra cost.

The Department agrees with commenters that, since alcohol symptoms are somewhat better known and easier to detect, more alcohol misusers than drug users are likely to be caught by observation, which justifies a lower random alcohol testing rate. (Of course, observation alone will not always detect employees with very low alcohol concentrations, unless they have an open bottle of liquor.) The deterrent effect of random alcohol testing may not equal that provided by random drug testing because the window for detection is limited by the rapid elimination of alcohol from the body. An individual who has alcohol in his or her system while performing safety-sensitive functions may be "negative" by the time he or she gets to the testing site and the testing is completed. In addition, there are many more programs in place to handle alcohol misuse problems than there were to handle drug use problems when we issued the drug rules. There is also no indication

that alcohol is a growing problem; drug use was, and there is still much evidence that strong steps must continue to prevent drug use from increasing. Consequently, we believe that a lower initial random testing rate is appropriate for alcohol.

For the above reasons, we believe we can permit the alcohol random testing rate to drop to 10 percent if performance criteria in our rules are met, but cannot permit a comparable drop in the drug testing random rate for a similar performance. In view of the small window of opportunity for detecting alcohol misuse, we agree with commenters that the added cost could be more useful if applied to other areas of the alcohol prevention program, such as training and employee assistance. On balance, we believe that an initial 25 percent random alcohol testing rate will best achieve deterrence and detection at a reasonable cost.

Many employers commented that they wanted performance-adjusted rates, where the random testing rate would be set according to each employer's random positive rate for the preceding year. These commenters stated that testing based on measures of results would provide an incentive for employers to try alternative deterrence methods. Labor agreed with employers on this issue. Adjusted-rate testing could be used to reward those employers who have adopted rehabilitation and treatment programs or who have low positive rates. A few preferred adjusted-rate testing by industry. Other commenters noted that providing flexibility with respect to the random testing rate would be extremely difficult to administer.

We agree that there is merit in using a random alcohol testing rate that is adjusted annually based on industry performance. To provide more incentive and flexibility, the rules allow those industries that demonstrate a very low positive alcohol random rate over two years, due to few employee alcohol misuse problems or the success of the alcohol prevention programs, to lower their random alcohol testing rate to 10 percent. Ten percent would be insufficient to protect public safety, at least as an initial testing rate. The number of tests conducted at a ten percent rate and the visibility of testing to employees, especially in medium and small companies, would be insufficient to obtain data about prevalence or deterrence of alcohol misuse. We could not reliably make decisions on data gathered with such a rate—at least not for a number of years. If those who say usage is extremely low are correct, when the data gathered at the initial 25

percent rate verifies this, the testing rate can be lowered.

The OA rules require employers to use an initial random alcohol testing rate of 25 percent. They provide that, after all employers have implemented the rules and industry-wide data for the first year is available, the OA Administrator will annually announce in the *Federal Register* the minimum required annual percentage rate for random alcohol testing applicable in that OA's covered industry during the calendar year following publication of the notice. Thereafter, each OA will determine the annual random alcohol testing rate for the industry regulated by the OA rule based on the reported violation rate (number of random alcohol tests results equal to or greater than 0.04 plus refusals-to-take random alcohol tests divided by the total random alcohol tests conducted plus refusals-to-take random alcohol tests) for the industry. The random rate adjustment indicated by industry performance will occur at the beginning of the next calendar year. (Thus, during calendar year 1997, an OA will receive results from its industry for calendar years 1995 and 1996 (the first year that industry-wide data will be available), evaluate them and publish in the *Federal Register* a determination of the need for the industry to adjust the random rate. Any such change would take effect on January 1, 1998. Please note that, once employers of all sizes are reporting data, a decrease in the rate would require two years of qualifying data and an increase in the rate would require only one year of data.) A refusal to take a random alcohol test will count as a positive for the purpose of calculating the industry random testing rate and count toward the number of random alcohol tests required to be conducted.

Determination of the violation rate is based on data obtained from employers through the annual Management Information System (MIS) reports they must submit by the following March 15th. We envision that each OA and the OST Drug Office will review the MIS data and that the OA Administrator will issue a determination within a few months. We believe that covered entities need approximately one-half year of lead time to adjust their procedures, make changes in any contracts and take other necessary action to adjust to an increase or decrease.

To make a decision, each OA will compare the violation rate to two specific criteria: 1 percent and 0.5 percent, respectively, to determine if the industry must change or maintain the random alcohol testing rate. If the

industry violation rate is 1 percent or greater during a given year, the random alcohol testing rate will be 50 percent for the calendar year following the OA Administrator's announcement that the rate must change. If the industry violation rate is less than 1 percent but greater than 0.5 percent during a given year (for two years if currently at 50 percent), the random alcohol testing rate will be 25 percent for the calendar year following the OA Administrator's announcement that the rate must change. If the industry violation rate is less than 0.5 percent during a given year (for two years if testing at a higher rate), the random alcohol testing rate will be 10 percent for the next calendar year. For example, an industry testing at a 50 percent random rate for alcohol can drop the rate to 10 percent if its violation rate drops below 0.5 percent for two consecutive years. Because of safety concerns, two years of data are necessary to justify lowering the rate and one year of data is sufficient to raise it. The two years cannot be averaged; a violation rate of 0.07 one year and a 0.11 violation rate the next year will not allow a drop in the random alcohol testing rate.

We selected 1.0 percent and 0.5 percent as appropriate performance standards. We would prefer zero positives but recognize this may be impossible. These levels represent a balance, permitting cost savings when usage remains very low, while ensuring that if deterrence is not maintained, the rates will increase. We selected the 1 percent violation rate as the rate adjustment standard based on the experience that the military and other workplace programs have had with deterrence-based drug testing. Their results reveal that no matter what rate is used for random testing, the testing programs will never achieve zero positives. There always is a constant group of "hard-core" individuals representing a fraction of 1 percent of the population who are detected positive over a period of time; these individuals are unaffected by deterrence-based testing because of addiction or belief in their invincibility. We also believe that a positive rate of 0.5 percent is achievable based on our limited data from the random roadside alcohol testing project, where rates below 0.5 percent were obtained, and our experience with DOT Federal employee drug testing where positive rates have decreased to 0.25 percent.

We recognize that because the reported violation rate is obtained from data whose precision is eroded by sampling variance and measurement error, and whose accuracy is diminished

by non-response bias, there is a greater risk that it diverges from the actual violation rate in the population. Each OA will be using MIS data collection and sampling methods that address these issues to the extent possible and make sense in the context of its particular industry. Where not all employers are included in the reported data, the OA will decide how many covered employers must be required to report or be sampled; this decision will be based on the number of employers (not otherwise required to report) that must be sampled to ensure that the reported data from the sampled employers reliably reflects the data that would have been received if all were required to report. However, we retain for our discretion the decision on whether the reported data reliably support the conclusion (e.g., based on audits of company records that show significant falsification of reports). If the reported data are not sufficiently reliable, the OA will not permit the random rate adjustment to occur.

We have decided to use industry violation rates (positive tests and refusals to test) as the performance benchmark rather than the employer violation rates urged by commenters. Company-by-company rates would be extremely difficult to implement and enforce, extremely difficult to apply to small companies, would require reports from all companies, could encourage cheating (especially in areas of heavy competition) and could excessively complicate the use of consortia. Although an individual company may have reduced incentive to lower its positive rate, industry organizations may pressure it to work toward a more favorable industry random alcohol testing rate. Industry-wide rates should be much easier to implement and enforce.

Implementation Issues. The lower random alcohol testing rates will create implementation problems, particularly for small employers and consortia (see discussion below). Small companies that do not participate in a consortium may have to test at a higher effective rate even after the industry rate has been lowered to meet other requirements. A very low number of dates on which tests are conducted will have a detrimental effect on deterrence. Therefore, to promote deterrence (and as required under the Department's drug testing rules), an employer must spread alcohol tests throughout the year. A very small company (e.g., one that has to test two covered employees) will not be permitted to only test employees once every few years. Rather, it will have to test at least once a year and establish a

program that will ensure that there is no period of time during which employees know testing "is done for the year". For example, if an employer is required to conduct only one to four tests and that number are completed by mid-summer, the employer's program must ensure that more tests could be conducted before the end of the calendar year. For example, such an employer could conduct random testing every quarter or could randomly select the month within the next 12 months for conducting the next test(s). Depending upon the month selected, the employer may in fact test more than once in a calendar year. For example, using a revolving calendar, the first selection is May 1994 for the year January 1994 to December 1994; the next selection must be for the 12 months from May 1994 to April 1995.

Another alternative is for small employers to join a consortium so that their employees are always subject to random testing. Although we have in a number of ways eased the burden on small employers, these restrictions that may raise the effective annual random rate are necessary to achieve deterrence in random testing in the context of allowing random rate adjustments. A small employer, of course, can achieve the benefits of a lower random rate without the higher costs of meeting the deterrence requirements if it joins a consortium. If the company is in a consortium, the employee is always subject to testing because he or she is part of a much larger pool and the necessary deterrence exists.

Under the Department's current drug testing rules, employers must conduct random drug tests at a 50 percent annualized rate; that is, the number of annual random tests conducted must equal half the number of the covered population. Elsewhere in today's *Federal Register*, the Department is publishing a separate NPRM that seeks comment on a proposed industry performance standard to adjust the random testing rate for the current drug testing programs. The proposal is designed to lower costs and maintain an equivalent level of deterrence of illegal drug use. The NPRM proposes to allow each OA Administrator to lower the random drug testing rate to 25 percent if its industry has a positive testing rate of less than 1.0 percent for two consecutive years (while testing at 50 percent); the rate will increase back to 50 percent, if the industry random violation rate is 1 percent or higher in any year. The Department is not proposing a system to adjust the drug random rates identical to that established for alcohol random testing for the opposite of the reasons stated.

above. It is more difficult to justify a possible lowering of the testing rate to 10 percent because the symptoms of drug usage are less well known and more difficult to detect by observation than symptoms of alcohol misuse. Moreover, random drug testing is a more effective deterrent than random alcohol testing because the window of opportunity for detection is greater; drug metabolites are present in the body far longer than alcohol. However, we agree with commenters that we still should provide an incentive for each industry to achieve a low random drug positive rate and reduce testing costs.

The random alcohol rate adjustments will have an impact on other aspects of random alcohol testing. If a given covered employee is subject to random alcohol testing under the alcohol misuse rules of more than one OA for the same employer, the employee shall be subject to random alcohol testing at the percentage rate established for the calendar year by the OA regulating more than 50 percent of the employee's safety-sensitive functions (or those that take the greatest percentage of the employee's time). If the employee's time is equally divided, the employer may choose the OA rule with the lowest random testing rate. If an employer is required to conduct random alcohol testing under the alcohol misuse prevention rules of more than one OA, the employer may (1) establish separate pools for random selection, with each pool containing the covered employees who are subject to testing at a different OA required rate; or (2) randomly select from all employees for testing at the highest percentage rate established for the calendar year by any OA to which the employer is subject. Consortia could meet different required random testing rates by setting up separate pools.

Many commenters, particularly employers, supporting random testing claimed that it would be less burdensome if they could combine their drug and alcohol random testing programs. They noted that using the same employee selection for both alcohol testing and drug testing would allow flexibility and be more cost effective, by minimizing the impact on an employer's operations. Labor supported combination testing, where an employee would not know in advance whether he or she was being tested for alcohol, drugs, or both, as the most effective type of program. The rules do not prohibit employers from combining random drug and alcohol testing. However, the possibility of different testing rates for drug and alcohol random testing may cause difficulties for employers interested in

combining their random testing programs. Differences in the testing rate for each program can be accommodated; for example, where an employer must use a 25 percent alcohol random rate and a 50 percent drug random rate, half (randomly selected) of the employees chosen for testing would be tested for both drugs and alcohol while the rest could be tested only for drugs. Other methods are possible so long as they meet the requirements of both programs. Of course, combined testing must occur around the time of performance of a safety-sensitive function to meet the requirements of the alcohol misuse prevention rules.

Reasonable Suspicion Testing

The vast majority of commenters supported the need for reasonable suspicion testing, although one commenter opposed it as unnecessary in view of existing company policies. We agree that this type of testing may be more valuable for alcohol than for illegal drugs. People are more familiar with the symptoms of alcohol intoxication than with those of illegal drug use. The presence of alcohol is easier to detect (at least at higher consumption amounts) from physical symptoms (e.g., odor of breath) or behavior (e.g., inability to walk a straight line) and more research has been done on how to train people to make these observations. Supervisor observation is not a complete solution, however; "practiced" drinkers often can mask symptoms (e.g., they use a breath spray or can walk a straight line) and avoid detection. Also, supervisors may have reasons to overlook employee alcohol use (e.g., sympathy for the employee, the desire to avoid confrontation, or the lack of a readily available replacement). The U.S. Army has found that supervisors have a tendency to underreport alcohol involvement in accidents (The Alcohol and Accidents Guide, February 1987).

The OA rules require employers to test covered employees for alcohol when the employer has reasonable suspicion to believe that the employee has violated the prohibitions in these rules or if the employee's behavior and appearance indicate alcohol misuse. The employer's determination that reasonable suspicion exists to require an alcohol test must be based on specific, contemporaneous, articulable observations by a trained supervisor concerning the appearance, behavior, speech, or body odors of the employee. Reasonable suspicion testing under these rules is authorized only if the required observations are made during, just preceding or just after the period of

the work day that the covered employee is performing a safety-sensitive function.

Several commenters wanted supervisors to be able to use long-term performance factors, such as abuse of sick leave, in making their reasonable suspicion testing decisions. In addition, they believed that requiring the observation to occur close to or during the performance of a safety-sensitive function is too restrictive. Some commenters thought that use of long-term factors would be appropriate only in conjunction with short-term indications of alcohol misuse; others opposed any use of long-term factors. The factors set out for determining when reasonable suspicion exists in the drug and alcohol rules are short-term in the sense that they focus on what a supervisor sees at the time of performance of safety-sensitive duties. The Department believes that this restriction is appropriate because it accommodates Fourth Amendment concerns by relating the determination of the need for testing to factors indicating possible alcohol involvement that may affect the employee's present ability to safely perform required safety-related tasks. For example, even if the supervisor does not smell alcohol, he or she legitimately could decide to test an employee who cannot hit the correct buttons to operate a vehicle (a required safety-related task), but should not test an employee simply because he or she comes in late that day. Constant lateness, for example, may result from an alcohol problem, but it is not a reasonable basis for suspicion of alcohol misuse; there are too many other possible explanations. The rules do not interfere with the supervisor's own authority to take appropriate action in response to longer-term factors (e.g., a long-term decline in work performance, patterns of absenteeism, lateness, or abuse of sick leave) that may violate company policies.

A covered employee is required to undergo reasonable suspicion testing for alcohol as soon as possible, because the body rapidly eliminates alcohol. Therefore, if a reasonable suspicion test is not conducted within two hours following the determination of reasonable suspicion, the employer shall prepare and maintain on file a record stating the reasons why the test was not conducted. If the test is not conducted within eight hours after the determination of reasonable suspicion, the employer shall cease attempts to conduct the test and shall state in the record the reasons for not administering the test. These records must be submitted to the appropriate

Department officials upon request. This record requirement and the reasons we are imposing it are similar to those for post-accident testing discussed above. (Please note this is a change from the NPRMs.)

A number of commenters expressed concerns that supervisors might abuse reasonable suspicion tests to harass unpopular employees and wanted strict requirements to prevent this possibility. Many wanted us to require that two supervisors make the decision to test (as in the existing drug testing rules) to limit possible harassment and to support management's case during future grievance and arbitration procedures. Others noted that a two-supervisor requirement would be impracticable because alcohol metabolizes so quickly and because in certain locations, many employees have only one supervisor available.

The alcohol final rules generally require a single supervisor trained in detecting the symptoms of alcohol misuse to make the required observations and determine the existence of reasonable suspicion. We agree with several commenters that alcohol testing is too time-sensitive to incorporate as a general rule the time it takes to consult a second supervisor before making the testing decision, which also is difficult or impossible in some transportation industry locations. In addition, symptoms of alcohol use are more widely-known and easier to detect than those of drug use so there is less need for corroboration. To protect against possible harassment of a specific employee, the supervisor who makes the determination that reasonable suspicion exists generally is prohibited from conducting the reasonable suspicion test on that employee. Comments were mixed on whether we should allow supervisors to base their decisions to conduct reasonable suspicion tests on third-party reports of alcohol misuse. We decided not to permit a supervisor to base such a decision on reports by a third person who has made the observations, because of that person's possible credibility problems or lack of appropriate training.

A few commenters suggested that supervisors document within two hours and annually report their reasons for conducting a reasonable suspicion test so that the OAs can check for harassment. We believe that the possibility that a review of company records would show whether particular individuals were harassed—i.e., tested without positive result too often—should help deter harassment. A couple of commenters envisioned holding supervisors liable for damages if the

results of the test did not confirm their suspicions. We believe it inappropriate to require action against a supervisor for ordering a test where the results are negative. Reasonable suspicion is not a guarantee of a positive result on an alcohol test. Other factors can result in behavior or appearance that can reasonably cause one to suspect alcohol misuse; that is why we require a test before requiring action for a rule violation. In addition, the supervisor may have been correct, but, by the time a test can be conducted, the alcohol may have passed through the employee's system.

Behavior and Appearance

Numerous commenters wanted to eliminate the proposed prohibition on employee behavior and appearance characteristic of alcohol misuse, because it is conceptually part of the reasonable suspicion prohibition and because it is so subjective. They noted that it would not be useful because managers do not always have daily contact with their employees. However, some commenters stated that they wanted the authority to remove an employee on behavior and appearance grounds when a reasonable suspicion test is not possible.

We agree that simple "behavior and appearance" of alcohol misuse involves a subjective determination and should not be considered prohibited conduct that triggers the full consequences of violating these rules without confirmation of such misuse by a positive test. As a result, the final rules have been changed from the NPRMs: under the reasonable suspicion testing provisions, an employer who observes such behavior and appearance must conduct a test; however, when it is infeasible or impossible to conduct a reasonable suspicion test in a timely manner (e.g., an EBT is unavailable or broken), the employee is not permitted to perform safety-sensitive functions for eight hours (or until obtaining a result below 0.02 on a test if an EBT subsequently becomes available within the 8-hour period).

The OA rules prohibit a covered employee from reporting for duty or remaining on duty requiring the performance of safety-sensitive functions while the employee is under the influence of or impaired by alcohol, as indicated by behavior, speech and performance indicators of alcohol misuse. They also prohibit an employer from allowing such an employee to perform or continue to perform safety-sensitive functions. However, since alcohol-related behavior tends to become apparent to persons without extensive training (such as that

provided by police) only at alcohol concentrations well above 0.04, it is unlikely that misuse would be detected in this manner at alcohol concentrations in the 0.02–0.04 range. Thus, there are important safety reasons for requiring that an employee be removed from his or her safety-sensitive function based on behavior and/or appearance alone if no testing devices are available. Another reason that we decided not to eliminate this provision entirely as requested by many commenters is because some employers do not believe that they otherwise have the authority to remove an employee who appears to be under the influence of alcohol in the absence of a test. We do not want an employer to allow a safety-sensitive employee to remain on duty for that reason.

Some commenters, particularly in the aviation industry, wanted to retain existing prohibitions on operating "under the influence" and while "impaired". To the extent some existing OA rules already permit removal of an employee based on observation alone, the employee has a right to an evidentiary hearing (e.g., as part of a certificate revocation action). The rules we have published today do not provide for a right to a hearing. For that reason, and because removal from a safety-sensitive function in the absence of a reasonable suspicion test involves a subjective determination, unverified by a test, and may provide an opportunity for the employer to harass an employee, we believe that lesser consequences should apply, i.e., removal from the safety-sensitive function until the next regularly scheduled duty period if at least 8 hours has passed. Removal for this reason does not require a SAP evaluation. Existing consequences in other OA rules that have "under the influence" or "impaired" language will continue in effect; any consequences that attach as a result of those rules could be imposed in addition to removing the employee from safety-sensitive function for eight hours. An employer's separate existing authority to remove employees is not affected by this provision.

Return-to-Duty Testing

The commenters split over whether return-to-duty testing should be mandated by regulation or left solely to the discretion of the employer; one commenter noted that it really is another "intelligence" test. Commenters who believed that the test should be discretionary disagreed whether the decision to test should rest with the employer (in consultation with the SAP) or the SAP alone. Some commenters stated that using a 0.02 standard is too

stringent. Others liked the provision as proposed.

The OA rules require each employer to ensure that a covered employee, who has violated any of these alcohol misuse rules, has been evaluated, treated (where indicated) and tested with a result indicating an alcohol concentration of less than 0.02 before returning to a safety-sensitive function. We disagree with those commenters who thought return-to-duty testing should be left solely to the discretion of the employer. We believe that compelling concerns about safety and possible recidivism justify imposing a return-to-duty test requirement for those employees returning to safety-sensitive functions after they already have demonstrated problems with alcohol. Similar concerns justify use of a stricter 0.02 standard for return-to-duty tests. In any event, under other provisions of the rules, employees could not perform safety-sensitive functions until they have a result lower than 0.02; since this test is specifically for return-to-duty, the application of the 0.02 standard is logical. A positive result on a return-to-duty test indicates a problem that has not been resolved; the employee cannot come back the next day to retake the test without seeing the SAP again. The decision to return the employee to safety-sensitive functions and to conduct the test ultimately belongs to the employer. The SAP's function is to advise the employer as to whether the employee has complied with any recommended program of treatment.

Given the potential for poly-drug misuse, the rules permit employers to conduct return-to-duty drug tests on an employee, when the SAP has reason to suspect drug involvement and recommends such testing. Any such testing must conform to the requirements of part 40. The opposite would be true as well. Employers would have similar authority to test for alcohol where an employee tested positive for drugs and the SAP had reason to suspect alcohol misuse. (The OA drug rules have been drafted or are being changed to permit this.)

Follow-Up Testing

Commenters disagreed as to whether follow-up testing should be required or discretionary. As with return-to-duty testing, they divided over leaving the follow-up testing decision to the employer or to the SAP. Several commenters thought that a requirement for follow-up testing would be too costly and burdensome for employers and might cause them to fire the employee instead. Others thought that the concept had merit, but that the rules should

require fewer tests over a shorter period of time, especially since the employee is also subject to random testing.

After identification of an employee's alcohol problem, there is a strong chance of recidivism and a need to ensure continued disassociation from alcohol misuse through periodic unannounced follow-up testing. We believe that a minimum number of follow-up tests is necessary to ensure public safety in view of various disincentives for imposing them, such as cost, the customary SAP preference for informal follow-up, and FRA's experience in its drug testing program (see below). In making the decision whether to return the employee to safety-sensitive duties, we assume the employer would determine whether, in its particular circumstances, the cost of hiring and training (and testing) a new employee would exceed that of testing a returned employee to ensure continued disassociation from alcohol. We agree with commenters that it is appropriate for the SAP to determine the employee's need for an individualized rehabilitation (if any) or follow-up program beyond the minimum specified here.

The OA rules require that each covered employee, who has been identified by a SAP as needing assistance in resolving problems with alcohol misuse and who has returned to duty involving the performance of a safety-sensitive function, shall be subject to a minimum of 6 unannounced, follow-up alcohol tests administered by the employer over the following 12 months. The SAP can direct additional testing during this period or for an additional period up to a maximum of 60 months from the date the employee returns to duty. The SAP can terminate the requirement for the follow-up testing in excess of the minimum at any time, if the SAP determines that the testing is no longer necessary. We believe that fewer follow-up alcohol tests over a shorter period would not provide sufficient deterrence of (or opportunity for detection of) alcohol misuse by an employee who has demonstrated a previous problem.

The FRA's experience under its drug testing rules with required follow-up testing for employees who tested positive for prohibited drugs illustrates the need for a minimum number of required follow-up tests. In 1991, FRA conducted a compliance review on a large railroad company and found that 9 of ten employees who had tested positive and were returned to service had received no follow-up tests during the next year. One employee received one follow-up test six months after

returning to work. One of the employees who had received no follow-up testing later tested positive on an FRA-required random drug test. The Department's Office of Inspector General (OIG) recently completed a review of the FRA's alcohol and drug program. The OIG reviewed follow-up testing practices on several railroads and found inconsistent procedures and a lack of follow-up tests. Its report recommends prescribing procedures for follow-up tests, including a minimum number of tests and a minimum period for follow-up testing. For the above stated reasons, we believe that we must require a minimum amount of follow-up testing.

The rules provide that the evaluation and treatment services may be furnished by the employer, by a SAP under contract with the employer or by a SAP not affiliated with the employer. In view of the "gatekeeper" function that the SAP has under the rules, we believe that the employer should designate the SAP. Experts note that, due to training and the profession's normal employee orientation, the SAP may be eager to place the employee back into the normal work environment, i.e., the safety-sensitive function, but reluctant to require testing by the employer. The SAP may prefer to conduct any necessary follow-up testing as part of an after-care or follow-up treatment program. While we recognize that placement of the employee back on the job as soon as possible without follow-up testing may help the employee, it could put public safety at risk. The SAP's customary professional loyalty to the employee "patient" would directly conflict with the safety responsibility of the employer. In order for this program to work and to ensure public safety, the SAP must recognize his or her obligations to be cognizant of the employer's responsibilities and need for a fair evaluation of the employee.

Given the potential for poly-drug misuse, the rules permit employers to conduct follow-up drug tests on an employee during the follow-up alcohol testing period, when the SAP has reason to suspect drug involvement. Any such testing must conform to the requirements of part 40. The opposite would be true as well. Employers would have similar authority to test for alcohol where an employee tested positive for drugs and the SAP had reason to suspect alcohol misuse. (The OA drug rules have been drafted or are being changed to permit this.)

The rules do not use the stricter 0.02 alcohol concentration standard imposed on return-to-duty tests for follow-up tests, even though the employee has previously demonstrated problems with

alcohol. In either case, the employee cannot perform safety-sensitive functions with an alcohol concentration of 0.02 or above. Unannounced follow-up tests of employees back on the job are similar to random tests. Because employers may find it convenient to conduct some follow-up testing at the same time as random tests, the consequences for follow-up test results must be the same as those for random tests. This will enable employers to conduct unannounced testing and combine follow-up testing with other types of testing, but avoid imposing total abstinence from alcohol on returned employees whose follow-up programs do not require it. We note that, under the Act, an aviation employee who has a second violation under the FAA alcohol misuse prevention rule will be forever barred from the employee's safety-sensitive function. Please see the preamble to the FAA rule for a more complete discussion of this consequence.

Retesting of Covered Employees With an Alcohol Concentration of 0.02 or Greater, but Less Than 0.04

Some commenters disagreed that there is any need to provide for retesting. Others used this issue as an opportunity to reiterate their opposition to the lesser consequences for test results indicating alcohol concentrations between 0.02–0.039.

The rules provide that if the employer chooses to permit the employee to perform a safety-sensitive function within 8 hours following the administration of an OA-required alcohol test indicating an alcohol concentration of 0.02 or greater but less than 0.04, the employer must first retest the employee. The employee can return to the safety-sensitive function if the retest results in an alcohol concentration of less than 0.02. However, the FHWA rule does not contain a retesting provision because of a statutory requirement that drivers found to have a measurable amount of alcohol in their systems must be removed for 24 hours. The FRA rule also does not contain this provision because it would conflict with its existing rules. Eliminating this option from the other OA rules would impose a hardship on some employers; the employer will make the decision whether retesting is necessary to accommodate its employment circumstances.

Handling of Test Results, Record Retention and Confidentiality

Retention of Records

We received very few comments directed to handling of alcohol recordkeeping requirements. Generally, those commenters wanted to shorten the record retention periods (the most popular option would reduce the proposed 5 years to 3 years and the proposed 2 years to 1 year).

To facilitate Department oversight and effective enforcement of the alcohol testing programs and to protect employee confidentiality, we are requiring each employer to maintain records of its alcohol misuse prevention program in a secure location with controlled access. One commenter wanted to know what that really means. The employer should lock the location (room, cabinet, or, if on computer, control access by password or other protections) and allow access only to persons with a legitimate need to see the records under these rules. The OA rules require employers to retain, for a minimum of five years, records of any employee alcohol test results indicating an alcohol concentration of 0.02 or greater; documentation of refusals to take required alcohol tests; equipment calibration documentation; and documentation of employee evaluations and referrals. They require employers to retain for a minimum of two years any records related to the collection process (except equipment calibration documentation) and training. Records of negative test results must be retained for a minimum of one year.

Generally, the rules require each employer to maintain the following specific records:

- (1) Records related to the collection process, including: Collection logbooks, if used; documents relating to the random selection process; EBT equipment calibration documentation; documentation of BAT training; documents generated in connection with decisions to administer reasonable suspicion and post-accident tests; and documents verifying existence of a medical explanation of an employee's inability to provide adequate breath for testing;
- (2) Records related to test results, to the refusal of any covered employee to submit to a required alcohol test and to an employee dispute over the result of an alcohol test;
- (3) Records related to other violations of these rules;
- (4) Records related to evaluations and return to duty; and
- (5) Records related to education and training.

We have decided to retain the retention periods as proposed because, considering the serious potential consequences of alcohol misuse, we believe it is important to be able to identify repeat offenders. In addition, the FAA has a need to track the number of repeated violations under its rule for mandatory permanent disqualification of an employee under the Act.

In the common preamble to the NPRMs, we asked whether we should require documentation of reasonable suspicion determinations. Very few commenters addressed this issue; some favored the requirement because such documentation might deter harassment of employees, but others opposed it as burdensome and a violation of employee privacy. The rules do not require documentation of reasons for determinations made to conduct reasonable suspicion tests, but if employers generate them, they must maintain the records. We are not requiring that employers report the specific test results of individuals—just aggregate numbers for reasonable suspicion tests conducted and resulting positives. This requirement should not burden employers and will protect employee privacy. Employers may want to monitor their reasonable suspicion testing positive rate to determine if their supervisors need additional training.

Reporting of Results in a Management Information System

For oversight purposes, each employer generally is required to compile for the OA that regulates it, at a minimum, an annual report summarizing the results of its alcohol misuse prevention program for each calendar year. This information will allow the Department to track progress in the programs and later make changes, if justified, that could reduce costs, ease implementation and enforcement, provide better employee protection, and/or increase benefits. Some OA rules require that all employers submit the data to the OA; others require a representative sampling of employers to submit the reports or a mix of required reports from some and a sampling of others. The OAs will rely on this data for program evaluation and enforcement purposes, as well as to adjust the random testing rates for alcohol. As noted earlier, FAA, FRA, FHWA, RSPA, and USCG separately published MIS rules on December 23, 1993, that describe the particular OA requirements for reporting information on drug testing (and alcohol testing for USCG). FTA's drug MIS requirements are in its final drug testing rule published elsewhere in today's *Federal Register*.

Generally, employers subject to more than one DOT OA alcohol rule must identify each employee covered by the regulations of more than one OA and report the total number of such employees broken down by category of covered function and by the OA. Before conducting any alcohol test on an employee regulated by more than one OA, the employer must determine which OA rule requires the test and then include the test result in the appropriate OA MIS report. Pre-employment and random testing data must be reported to the OA that covers more than 50 percent of the employee's function. Post-accident and reasonable suspicion testing results, however, must be reported to the OA that covers the function the employee was performing at the time of the accident or determination of reasonable suspicion. Finally, return-to-duty and follow-up results must be reported to the same OA that received the initial results that led to the employee's removal from the safety-sensitive function. In response to one commenter's concerns about confidentiality of employee results, we note that the employer must provide aggregated, not individual, information under the MIS.

Most of the comments addressed the drug MIS requirements; we received very few concerning the alcohol MIS proposal. Since the MIS requirements for drugs and alcohol are essentially similar, the Department's responses to specific comments on the drug MIS requirements, which are addressed in the preamble to the drug MIS rules published December 23, 1993 (FTA's MIS comments are addressed in the preamble to its final drug rule), also apply to the alcohol MIS requirements.

Commenters generally expressed concerns about ensuring unimpeded access to employee testing information kept by third-party providers, e.g., consortia. The employer is responsible for the accuracy and timeliness of each report submitted by it or a third-party service provider acting on the employer's behalf. If necessary, the employer should ensure by contract or other means access to employee testing information held by a third-party provider.

Employers required to submit the annual reports must do so no later than March 15 of each year for the preceding calendar year on the specified form. Each report will contain a number of information items relevant to program evaluation or enforcement. Eventually, we plan to merge the alcohol and drug testing reporting requirements where practical to permit one annual report and to eliminate any duplicative

information items. The Department is committed to developing the capability for processing electronic submission of these reports where such capability is not currently available.

Access to Facilities and Records

To preserve employee confidentiality, the rules generally prohibit employers from releasing information pertaining to an alcohol test of a covered employee or any violation of these rules, except as required by law. They provide, however, that the employee is entitled, upon written request, to obtain copies of any records concerning the employee's use of alcohol, including alcohol test records. The rules permit the employer to disclose information arising from the results of an alcohol test administered under these rules or from the employer's determination that the employee violated any prohibitions in these rules to the employee or in the context of a proceeding relating to: (1) An employee benefit; (2) DOT agency action against the employee (e.g., an action to revoke a certificate); or (3) an NTSB safety investigation. Employers must promptly provide any records requested by the employee, but cannot make access to an employee's records contingent upon payment for records other than those specifically requested. The bundling of requested records with unrequested material at much higher cost has been a problem under the drug rules. Employers also will have to release information as required by law, including court orders or subpoenas. Please refer to part 40 for additional discussion.

The rules generally require an employer to permit access to all facilities involved in its alcohol testing program and make available copies of all test results and any other alcohol program records, upon request, to the Secretary of Transportation or any OA with regulatory authority over the employer or any of its covered employees. In addition, upon request by the NTSB as part of an accident investigation, employers are required to disclose information related to the employer's administration of a post-accident alcohol test following the accident under investigation. FTA's rule requires the employer to disclose test results to States to be consistent with obligations placed on States under FTA's State Safety Oversight rule. See the preamble to the FTA rule for a further discussion of this. RSPA's rule requires the employer to permit access to facilities and make available test results and records to a representative of a State agency with regulatory authority over the employer.

Several commenters raised questions about the reporting of confidential information on individuals and opposed mandatory release of employee test results to subsequent employers and other parties because of unspecified liability concerns. Some commenters expressed their support for employer provision of test results in appropriate circumstances; a few others opposed allowing employers to require employees to authorize the release of previous test results as a condition of employment.

Generally, the rules require an employer to release information regarding an employee's records as directed by the specific, written consent of the employee authorizing release to an identified person. In view of the fact that these rules permit employers to rely upon negative pre-employment alcohol tests conducted by other employers within the preceding six months, we believe that it is appropriate to require a prior employer, upon written request from the employee, to make records available to a subsequent employer. This pre-employment exception, which can significantly reduce hiring costs for some employers, might not otherwise be available to them. Since the previous employer would release the records only with the written consent of the employee for a specific limited purpose, commenters' liability concerns appear to be unfounded. To preserve the employee's confidentiality, the rules prohibit the identified person or recipient employer from subsequently disclosing the records, except as expressly authorized by the terms of the employee's written request. Please refer to part 40 for additional discussion.

These rules do not prohibit employers from using their own authority to require applicants to release previous test results. We believe that employers should be able to protect themselves from alcohol misusers who move from job to job as they are detected. A prudent employer can ask an applicant to request this information from former covered employers as a condition of employment and not hire the applicant until satisfactory information has been received. If the applicant does not provide this consent, the employer simply could choose not to hire the applicant for a safety-sensitive position. Of course, an employer must conduct a pre-employment test when a previous employer does not respond (e.g., had gone out of business, could not be located, failed or refused to provide the requested information).

Consequences for Employees Engaging in Alcohol-Related Conduct

Removal From Safety-Sensitive Function/Required Evaluation and Testing

In general, the OA rules prohibit a covered employee who has engaged in conduct prohibited by any of the OA rules from performing safety-sensitive functions until he or she has met the conditions for returning to such work, which include a SAP evaluation, compliance with any required treatment program, and a successful return-to-duty test with a result below 0.02. The rules require employers, if they have determined that the employee has violated these rules, to ensure that the employee does not perform or continue to perform safety-sensitive functions.

Some commenters expressed the opinion that employers should determine the appropriate consequences for a violation of these rules. We disagree; there may be situations where a conflict exists between protecting public safety and an employer's strong economic incentive to keep an employee who misuses alcohol on the job. We believe that we need to establish the appropriate consequences for violation of these rules to protect public safety and to ensure their uniform application to similarly-situated employees to the extent possible. The rules do not prohibit an employer with authority independent of these rules from taking any other action against an employee.

A few commenters stated that employers who remove an employee from a safety-sensitive function should not be obligated to place that employee in another position or compensate the employee. All these rules require is removal from safety-sensitive functions. We leave the specific conditions under which an employee is removed, such as whether or not the employee is paid or moved to another non-safety-sensitive position, to employer policies or collective bargaining.

A few commenters wanted the consequences to be the same for all of the OA rules. Some of the OA rules do impose different consequences; these result from differing statutory requirements and the need to place these programs within the frameworks of the OA's existing safety regulations. The Act mandates harsher treatment of certain aviation employees that violate these rules. FHWA had to fit its rule within a statutorily-required system of consequences for violations of its safety requirements. (See the FAA and FHWA rules for a specific discussion of these differences.)

Other Alcohol-Related Conduct

Continuing the argument over the appropriate prohibited alcohol concentration, some commenters on this section wanted to eliminate the lesser consequences for a 0.02–0.039 alcohol concentration and impose the full consequences under these rules on any test result at 0.02 or above, while others believed that no action should be taken against an employee with a result below 0.04. We disagree with commenters who want no action taken against an employee at alcohol concentrations below 0.04. Although the Department is not making alcohol concentrations below 0.04 a violation of the rules requiring removal from safety-sensitive functions until evaluation and, if necessary, treatment, we are concerned about employees whose alcohol test indicates some alcohol in their system. As noted earlier in this preamble, an alcohol concentration of .039 may not warrant evaluation and treatment, but it may have an adverse effect on that individual's abilities to perform safety-sensitive functions. Alternatively, the individual's blood alcohol curve may be rising, (i.e., the individual may have just consumed enough to ultimately produce an alcohol concentration of 0.04 or greater, but the alcohol is just entering the bloodstream and, at the time of testing, the alcohol concentration is below 0.04 and rising). Permitting such an employee to continue performing safety-sensitive functions, when we know there is alcohol in his or her system, would violate our (and the employer's and employee's) safety responsibility.

Therefore, in addition to the 0.04 alcohol concentration prohibition, the rules require removal of covered employees found to have an alcohol concentration of 0.02 or greater but less than 0.04 from safety-sensitive functions, until the employee is retested with a result below 0.02, or until the start of the employee's next regularly scheduled duty period, if it occurs at least eight hours following administration of the test. If the retest result is above 0.04, the employee has violated the prohibition against having an alcohol concentration greater than 0.04. The employee will then be required to meet the conditions for returning to safety-sensitive functions. The rules do not prohibit the employer with authority independent of these rules from taking any other action against an employee based solely on test results showing an alcohol concentration greater than 0.02.

The OA rules and the part 40 alcohol testing procedures treat any indicated

alcohol concentration reading of less than 0.02 on an evidential breath testing device (EBT) as "negative." Given the limits of technology for measuring alcohol concentration in body fluids or breath, the rules use 0.02 as the threshold for establishing any measured alcohol concentration. Below this level, we can not be certain an individual actually has alcohol in his or her system. Readings below 0.02, therefore, have no significance for any purpose under our rules.

Use of Back Extrapolation

Most commenters opposed allowing the use of back extrapolation because of its difficulty and uncertainty in application and because it could infringe upon an employee's legal use of alcohol. Back extrapolation is the calculation used to determine alcohol concentrations over time based on an average rate of alcohol metabolism. It is most generally used to determine whether the alcohol concentration during the performance of the safety-sensitive functions (e.g., at the time of the accident) was actually greater than a specific concentration obtained at a later time. The OA rules require action only based on actual readings on the EBTs. They do not permit back extrapolation because, given the wide individual variations in alcohol metabolism, it creates too many uncertainties in the context of these programs. This prohibition would not prevent an OA from making use of back extrapolation in certain situations. Some existing OA rules permit the use of back extrapolation through expert scientific testimony in reasonable cause and post-accident cases conducted with appropriate due process protections. The rules that we are publishing today do not provide such protections. Those situations are different from the use of back extrapolation by employers in interpreting the results of tests conducted under part 40.

The rationale for back extrapolation is based on studies that show that the average rate of elimination of alcohol from the bloodstream is approximately .015 percent per hour, though this rate may well decline at low concentrations (0.02 and below). Individuals' rates of alcohol elimination are very often not "average," however. Further, it is ordinarily not known when the individual last ingested alcohol or how much alcohol he or she consumed. All of these factors make back extrapolation subject to substantial inaccuracy. Such analysis requires a number of "assumptions." Some of the assumptions relate to the individual subject (e.g., whether there is healthy

liver function, whether food was ingested before consuming alcohol, or other metabolic differences), some to facts or claims that may be supplied by the individual (e.g., no on-duty consumption, no consumption during the pre-duty abstinence period), and others to data that can be supplied by the employer (e.g., when the event occurred that triggered the test, when the test occurred). It is not only desirable but necessary for such analysis to be conducted by an expert in forensic toxicology.

We have decided not to permit back extrapolation of alcohol test results under these rules, because it would base serious consequences on the variable and uncertain results of this type of analysis. However, the requirement that employers remove persons with indicated alcohol concentrations of 0.02 or greater and less than 0.04 from safety-sensitive functions for a period of not less than 8 hours or until they retest below 0.02 will achieve some of the goals of back extrapolation.

Alcohol Misuse Information, Training, and Referral

Employer Obligation to Promulgate a Policy on Alcohol Misuse

The rules require each employer to ensure that each employee receives educational materials that explain these alcohol misuse prevention requirements and the employer's policies and procedures with respect to meeting those requirements prior to the start of alcohol testing. Each employer is required to provide written notice to every covered employee and to representatives of employee organizations concerning the availability of this information. Under the rules, the materials must include: the identity of a contact person knowledgeable about the materials; factual information on the effects of alcohol misuse on personal life, health, and safety in the work environment; signs and symptoms of alcohol misuse (the employee's or coworker's), particularly at low concentrations; where help can be obtained; available intervention methods, including referral to an employee assistance program (EAP), other SAPs and/or management; categories of employees subject to testing; what period of the workday or what functions would be covered by the rules; a description of prohibited conduct and the circumstances that trigger testing; testing procedures and safeguards; an explanation of what constitutes a refusal to submit to testing and the attendant consequences; and the consequences of violating the rules (as

well as lesser consequences for employees found to have an alcohol concentration of 0.02 or greater but less than 0.04.)

Many commenters believed that simply providing the above information is not sufficient to ensure that employees understand the requirements of these rules and their consequences. This and other comments on this provision related to employee training are addressed below.

Self-Identification/Peer-Referral Programs

Since our primary purpose is to deter alcohol misuse and keep employees who have alcohol in their systems from performing safety-sensitive functions, employees should be able to identify themselves as unfit to work. A few commenters wanted to be able to "mark-off". Some segments of the transportation industry already have self-identification programs that allow an employee to decline without penalty to perform or continue to perform his or her job if the employee knows that he or she is or may be impaired by alcohol. We do not require such programs, because we believe that they are a matter more appropriate for collective bargaining and employer policy. The successful implementation of such programs depends upon joint labor-management commitment to an alcohol/drug-free work environment. However, we encourage employers to establish self-identification or peer-referral programs and encourage employees to use them.

However, such programs cannot interfere with the conduct of the alcohol tests required by these rules. Employers who have set up such programs must ensure that employees are not allowed to self-identify after they know that they have been selected for testing. This would compromise safety and frustrate the goals of these programs. The rules do not interfere with an employer's discretion to impose its own sanctions against self-identifying employees, so long as the sanctions are not premised on our rules. Such a program could permit a covered employee to take a voluntary alcohol test to determine whether the employee would be in violation of these rules if the employee were to perform safety-sensitive functions (but not after the employee has been selected for DOT-required testing); there would be no Federal consequences or requirements pertaining to the test or its results, however, since that kind of test is not required by DOT rules.

In addition to program information, the materials also may describe any

peer-identification or self-identification programs or procedures that employers offer or are associated with under which a covered employee may decline to perform or continue to perform safety-sensitive functions without penalty when he or she may be in violation of these rules, including any limits on the programs. The employer also may include information on additional employer policies with respect to the use or possession of alcohol, including any consequences for an employee found to have a specified alcohol concentration, that are based on the employer's authority independent of these rules. These additional policies must be clearly communicated and identified as based on the employer's independent authority.

Training for Supervisors

Commenters who addressed the issue of supervisor training or education requirements proposed in the OA rules generally supported one or a mix of the following: the necessity for annual or other recurrent supervisory training; the necessity for 2 hours or more of supervisory training; the adequacy of one hour of supervisory training; or a mandatory requirement for supervisory training with the amount or length of training left unspecified. For example, those who preferred a particular amount of time for training split between a one-time training requirement and an annual or other recurring training requirement.

Those commenters who supported recurrent or annual supervisory training requirements expressed the belief that supervisory personnel need refresher or ongoing education to maintain and improve skills and knowledge necessary to making effective decisions regarding reasonable suspicion alcohol testing. These commenters cited experience with one-time training for supervisors that did not provide sufficient exposure to the problems associated with confronting and identifying problem employees. Other commenters cited anecdotal information that reasonable suspicion testing was more appropriately and frequently used when supervisory training was part of an annual or periodic training program.

The OA rules require employers to ensure that persons designated to determine whether reasonable suspicion exists to require an alcohol test receive at least 60 minutes of training on the physical, behavioral, speech, and performance indicators of probable alcohol misuse, particularly those associated with lower concentrations of alcohol. We believe that this amount of training time is adequate for this specific purpose and in view of the fact

that the symptoms of alcohol misuse are commonly known and recognized. We believe that retaining the one-hour training requirement best balances the benefits of supervisor training with its high costs to employers. Additional supervisor training beyond a mandatory one-time, one-hour minimum may be desirable, but requiring it would significantly increase the costs imposed by these rules. At this time, we lack definitive information to corroborate the cost of additional training with quantifiable benefits that would justify imposition of those additional costs on the transportation industries. Employers may, of course, provide additional information or annual (or other recurrent) training if they desire.

Several commenters requested that the rules combine drug and alcohol training for supervisors. These commenters argued that training would be more effective if viewed in the context of all substance abuse rather than divided into separate courses for drug and alcohol abuse. Employers are free to combine supervisor training for alcohol misuse detection with the comparable training for drug use detection currently required by the OA drug testing rules for a total of two hours to minimize costs and inconvenience. Please note that FRA will retain its existing combined three-hour requirement for alcohol and drug abuse training for supervisors.

A few commenters suggested that the requirements for supervisory training should be content- rather than time-specific. These commenters recommended that the rules specify core or essential components of the curriculum and employers would develop the supervisory courses accordingly. This approach reflects a preference for criterion or performance standard training requirements, rather than training based on a "classroom hours" concept. We have decided not to establish mandatory performance-based training because of the difficulty of developing meaningful specific core course components that cover various different industry situations and the administrative burden of evaluating whether or not employers have met the performance standards. We would rather allow employers the flexibility of tailoring supervisor training to their particular industry and programs. We do, however, take this approach with required BAT training, because that is much more technical and specific and must be the same for part 40 testing in all transportation industries.

Employee Training

Commenters presented many of the same arguments on the issue of mandatory employee training as they did regarding supervisory training. Various commenters suggested that mandatory recurrent or periodic employee training would be advantageous and more effective as a prevention or deterrent strategy than testing. Commenters also suggested that the rules should combine alcohol awareness education with drug abuse education to address the total substance abuse problem. Some commenters opposed mandatory employee training because of cost concerns.

Most comments on the issue of employee education criticized the lack of specific proposed requirements for mandatory employee education and training on alcohol misuse. These commenters argued that the proposals to provide employees printed literature and information were inadequate and, according to some, a waste of time and money. They expressed the belief that structured, "classroom" type training is more effective in presenting information about drug and alcohol abuse and to increase awareness and prevention of alcohol misuse. A few commenters argued that it is irresponsible and unnecessarily punitive to impose a comprehensive alcohol testing program with specific prohibitions on alcohol misuse, without requiring training for employees to be certain they understand the prohibited conduct and the consequences of misconduct.

We believe motivating employees about safety in the workplace and good health is important to making an alcohol misuse prevention program work. Because the primary objective of any effective alcohol misuse program is deterrence rather than detection, it is especially important that, before any testing is begun, employers make their employees fully aware of the dangers of alcohol misuse in their jobs, advise them where help can be obtained if they have a problem with alcohol use, and alert them to the potential consequences for people who violate these rules.

These rules require that employers give covered employees alcohol misuse information, but do not require classroom training for nonsupervisory employees. Although such training may be desirable, industry-wide mandatory employee classroom training would be prohibitively expensive. In the highway area alone, a one-time, one-hour training requirement for approximately 6.3 million employees, with a large amount of turnover, at an average hourly wage of \$14.50 plus travel time, cost of

materials, etc., would cost in excess of \$100 million. At this time, we lack definitive information to corroborate the cost of training with quantifiable benefits that would justify imposition of these costs. Because of the large number of employees covered by these rules, the widely varying relationships between employer and employee, and the difficulty in ensuring the effectiveness of such wide-spread training, we believe it appropriate to allow employers the discretion to determine the best means of educating their employees beyond the minimum requirement to distribute informational materials.

Some researchers claim that education is more effective in preventing alcohol misuse than sanctions or enforcement initiatives. For example, a Boston University researcher concluded that social pressure and publicity "may be as important as government regulations in reducing impaired driving and fatal crashes." (quoted in "USA Today," Wednesday, August 3, 1988.) In the area of impaired driving deterrence, NHTSA believes that the most effective programs are those that combine education and enforcement. Information and education programs, in the absence of enforcement activities or sanctions, have never been shown to have an impact on reducing alcohol-related fatal crashes. Conversely, scores of studies have found that programs involving enhanced enforcement, roadside sobriety checkpoints, and the use of sanctions such as license suspensions frequently have resulted in significant reductions of alcohol-related fatalities. Although there is disagreement on the effectiveness of education alone, it appears that using education as an adjunct to other deterrent measures, such as those in these rules, will make both more effective.

We recognize that it may be difficult to get the attention and support of workers by handing them literature or displaying various materials on a bulletin board. In conjunction with the implementation of the rules, the Department also plans to distribute educational materials and conduct seminars designed to help employers increase employee awareness of the risks of alcohol misuse by those who perform safety-sensitive functions. The Department took similar action in the drug area.

Referral, Evaluation, and Treatment

Numerous commenters expressed concern that the NPRMs did not go far enough in ensuring that employees would get access to needed assistance and treatment. They felt that even

though the proposed rules require "evaluation and assessment" by a SAP, they do not protect employees who violate the alcohol misuse provisions from termination, and, therefore, the access to treatment via the SAP evaluation is a sham; a paperwork exercise. Several commenters favored mandatory employer-provided or paid rehabilitation, citing our proposals as a cynical violation of the Congressional mandate to provide an opportunity for rehabilitation. Some commenters, particularly labor and union groups, expressed the view that the rules should specifically guarantee that employees who violate the regulations are evaluated by a SAP and provided access to treatment, regardless of personnel actions taken by the employer. Many commenters, however, opposed mandatory employer-provided or paid rehabilitation.

The Act requires that an opportunity for treatment be made available to covered employees. To implement this mandate, these rules require an employer to advise a covered employee, who engages in conduct prohibited under these rules, of the available resources for evaluation and treatment of alcohol problems, including the names, addresses, and telephone numbers of SAPs and counseling and treatment programs. They also provide for SAP evaluation to identify employees with alcohol misuse problems. The employer has no similar obligation to applicants who refuse to submit to or have a positive result on a pre-employment test; this obligation runs only to current employees. The rules do not require employers to provide or pay for rehabilitation or to hold a job open for an employee with or without salary; the costs of such requirements could be prohibitive and could jeopardize the success of this program. In the drug testing rules, the Department decided that it was inappropriate to establish a Federal role in mandating that employers provide for rehabilitation and that it should be left for management/employee negotiation. The same logic applies here and the Department has decided not to require employer-provided rehabilitation in these rules. We believe that the rules' provisions concerning evaluation adequately address the Act's requirements.

Many commenters noted that EAPs have proven successful in offering employees with alcohol problems an avenue to non-punitive resolution of their problems and in offering employers the ability to return employees to the workforce who might otherwise have been fired. Aviation

employers pointed to the FAA-supported Human Intervention and Motivational Study (HIMS) as a particularly effective program, with its combination of alcohol awareness training for supervisors and peers, rehabilitation, return to duty/medical certification process, and intensive follow-up monitoring of recovery. Overall, the success rate for alcoholic pilots identified through the HIMS or related programs has been about ninety percent. Some transportation employers have established similar programs for all of their employees. A number of these commenters also expressed their concerns that resources currently dedicated to EAPs would have to be shifted to support the new alcohol testing requirements, resulting in the reduction or elimination of existing EAP services.

We recognize that these programs will be costly and that, in specific circumstances, employers may decide that they have to divert funds from an EAP to conduct the required alcohol testing and prevention programs. The primary safety objective of these rules is to prevent, through deterrence and detection, alcohol misusers from performing safety-sensitive functions. The necessary resources must be provided to accomplish this objective. We hope that employers do not have to divert resources from EAPs to achieve this. We recognize the value of rehabilitation and encourage those employers who can afford to provide it to do so through established health insurance programs, since it helps their employees, benefits morale, is often cost-effective and ultimately contributes to the success of both their business and their testing programs. Please note that repeated provision of access to rehabilitation services after "positive" testing, followed by repeated reinstatement and repeated violations, may raise public safety and liability concerns for employers. It also could dilute the deterrent value of testing programs and encourage further misuse of alcohol.

Commenters also addressed the issue of the role of the SAP in return-to-duty determinations. Many of these commenters felt that the NPRMs were not clear in delineating how and by whom the decision of an employee's return to safety-sensitive function would be made. Some of these commenters believe that the SAP should play a crucial role in advising or recommending return-to-duty actions to employers.

The rules provide that the evaluation may be provided by a SAP employed by the employer, by a SAP under contract

with the employer, or by a SAP not affiliated with the employer. A SAP will evaluate each covered employee who violates these rules to determine whether the employee needs assistance resolving problems associated with alcohol misuse and refer the employee for any necessary treatment. Before returning to duty, each employee identified as needing assistance must (1) Be evaluated again by a SAP to determine whether the employee has successfully complied with the treatment program prescribed following the initial evaluation, (2) Undergo an alcohol test with a result of less than 0.02 alcohol concentration, and (3) Be subject to a minimum of six (6) unannounced, follow-up alcohol tests over the following twelve (12) months. Compliance with the prescribed treatment and passing the return-to-duty alcohol test do not guarantee a right of reemployment or return to safety-sensitive duties; they are preconditions the employee must meet in order to perform safety-sensitive functions. The decision on whether to return the employee to his or her job we leave to the employer. The choice of SAP and assignment of costs should be made in accordance with employer/employee agreements and/or employer policies.

In the common preamble to the NPRMs, we proposed categories of persons eligible to be SAPs and asked if other categories should be included. Numerous commenters complained that the proposed definition was too restrictive. The National Association of Alcoholism and Drug Abuse Counselors (NAADAC) organized a widespread effort for its membership to send comments supporting the position that certified addiction counselors were the most qualified professional or occupational group to serve as SAPs. These comments tended to emphasize NAADAC standards and certification requirements, especially in counseling, treatment and rehabilitation of alcoholics and addicts. Many commenters certified by other State or local boards also presented arguments for their inclusion in the definition of a SAP. A few commenters suggested that physicians, social workers, and psychologists do not generally have training or skills specific to alcohol and drug abuse diagnosis or treatment.

The final rules define the SAP, as proposed, to include a licensed physician (with a Medical Doctor or Doctor of Osteopathy degree) with knowledge of and clinical experience in the diagnosis and treatment of alcohol-related disorders (the degrees alone do not confer this knowledge), or a licensed or certified psychologist, social worker,

or employee assistance professional with knowledge of and clinical experience in the diagnosis and treatment of alcohol-related disorders. In response to comments, we also have included in the definition alcohol and drug abuse counselors certified by the NAADAC Certification Commission, a national organization that imposes qualification standards for treatment of alcohol-related disorders. The commenters provided information showing that the training and experience necessary to meet NAADAC standards are sufficient for participating as a SAP in our alcohol misuse prevention programs. We rejected commenters' suggestions that the definition include State-certified counselors, because the qualification standards vary dramatically by State; in some States, certified counselors do not have the experience or training we deem necessary to implement the objectives of our rules. State-certified addiction counselors can, of course, take the NAADAC competency examination to become a certified alcoholism and drug abuse counselor. The rules require that all persons in the categories listed in the definition must have knowledge of and clinical experience in the diagnosis and treatment of alcohol-related disorders to qualify.

A few commenters expressed concern about the relationship of the SAP to the treatment or rehabilitation staff or facility. These commenters specifically addressed potential conflicts of interest, a "referral-to-self" practice, and the objectivity of return-to-duty evaluations. Many of these commenters believed that the rules should establish specific parameters that outline the SAP's duty or obligation to the employer as well as protections for employees against unscrupulous or unethical SAPs who would use the evaluation and assessment process to foster their own practice or treatment facilities.

Professional organizations, such as the Employee Assistance Professionals Association, prohibit their members from making referrals for treatment to their own practice or to agencies from which they receive financial remuneration. We want to avoid conflict-of-interest problems that could arise where the SAP is involved in both the evaluation and treatment phases of employee assistance, which could lead to recommendations for inadequate or inappropriate treatment for the employee and/or the imposition of unnecessary costs on both employers and employees. For example, a SAP might recommend a one-time misuser for a 30-day treatment program in which the SAP has a financial interest or send

an alcoholic through the SAP's own outpatient treatment program. Therefore, the rules generally require the employer to ensure that a SAP who determines that a covered employee requires assistance in resolving problems with alcohol misuse does not refer the employee to the SAP's private practice or to a person or organization from which the SAP receives remuneration or in which the SAP has a financial interest. However, this requirement could impose hardship and the unnecessary costs of requiring two different sources of assessment and treatment on employers in remote areas or in situations where employee assistance (including assessment and treatment) is provided by contract or through a health insurance program. Therefore, the rules do not prohibit a SAP from referring an employee for assistance provided through (1) a public agency; (2) the employer; (3) a person under contract to provide treatment for alcohol problems on behalf of the employer; (4) the sole source of therapeutically appropriate treatment under the employee's health insurance program; or (5) the sole source of therapeutically appropriate treatment reasonably accessible to the employee.

Some commenters wanted a medical review officer (MRO) to review and interpret alcohol test results. Since the determination made in alcohol tests required by these rules is whether there is a prohibited concentration of alcohol in an individual's system, regardless of the source, there is no need to require an MRO to interpret positive test results, as required by the DOT drug testing rules. There is no "alternative medical explanation" for the prohibited alcohol concentration, so there is no role for an MRO. The mental health and/or medical professionals to whom the employee is referred can evaluate the employee's problems, if any, associated with the alcohol misuse. A SAP will then determine whether the employee has complied with any recommended treatment program. In some OA rules, where the employee operates under a certificate or license, a licensed physician must certify, in conjunction with a medical examination, whether the employee can return to work.

Other Issues

Flexible Approaches

As in the drug testing rules, we want to provide program flexibility to allow employers to carry out their programs in a more efficient, cost-effective manner and to ease the compliance burden on small businesses. Testing, for example, can be conducted by the employer, an

outside contractor or program administrator, a consortium, a union, or any other entity. The use of consortia has worked well in the drug testing area; in fact, it is the predominant method of compliance in some industries, particularly among smaller employers. We have delayed implementation of the alcohol rules for smaller employers by an additional year to enable them to join established consortia or large employer testing programs, rather than have to establish their own programs.

The OA rules have specific provisions to make it easier for smaller employers; FRA is retaining its existing exemption from its drug and alcohol rules for railroads with 15 or fewer employees that do not engage in joint operations. (These entities are not considered sufficiently safety-sensitive to be subject to testing, since they tend to operate on private track at slow speeds.) FRA, which requires covered employers to submit plans for their alcohol misuse programs, imposes significantly reduced plan requirements on smaller employers.

Employers may find it more cost-effective and convenient to conduct alcohol testing, particularly random testing, at the same time they conduct drug testing. Because we require alcohol testing at or near the time of performance, however, all random and reasonable suspicion drug testing also would have to occur at such times. In addition, the testing would have to take into account differences in the alcohol and drug random testing rates for the employer's industry. For random testing, employers can randomly choose the employee's number and then test the employee for both drugs and alcohol the next time he or she performs safety-sensitive functions. As described earlier, we are allowing performance-based random alcohol testing rate adjustments and initiating additional rulemaking to provide for greater flexibility in testing methods.

Motor Carrier Safety Assistance Program (MCSAP Option)

In the OA NPRMs, we sought public comment on whether the post-accident and random (or other) roadside testing could be conducted by state and local law enforcement officials under the FHWA Motor Carrier Safety Assistance Program (MCSAP), which is a Federal/State cost reimbursement and matching grant-in-aid program to increase commercial motor vehicle safety, or a similar program. The FHWA NPRM specifically proposed this option. Under the MCSAP, participating States would have to submit a random (or other) alcohol testing plan as part of their

application for FHWA MCSAP funding. The random alcohol testing plan component would conform to the requirements of these rules.

Recognizing that statutory changes to implement the MCSAP option would be necessary, we sought public comment on whether involving State and local authorities in alcohol testing would work for the various types of testing in the different transportation industries. Since States already have some equipment and their law enforcement officials already are trained in using that equipment, overall costs might be less; user fees could be imposed on covered employers to cover State costs. As neutral, third-party testers, their tests might be better accepted by employees. Due to the fact that local officials may reach an accident first, they could help in determining who was involved in the accident and also conduct tests sooner.

Commenters were divided on this proposal. Most employers, particularly motor carriers, liked the option because it would impose testing costs on State and local authorities, rather than on individual motor carriers, especially independent owner-operators. They opposed the proposed imposition of user fees to support this program. One commenter suggested that the Federal government should pay local or State governments to perform alcohol testing. A few employers noted that roadside testing would be too time-consuming and would disrupt their closely-timed shipment and travel schedules; they prefer employer-based testing where they have more control over scheduling. They also noted that the proposal would reduce training costs because the law enforcement officers already are trained in conducting alcohol tests. The States and local authorities, including MCSAP agencies, opposed this option because of the costs (another unfunded mandate imposed on States by the Federal Government), diversion of law enforcement personnel from traditional functions, and lack of legal authority to conduct alcohol tests under their existing statutes without the requisite probable cause. They believed that without additional appropriations, the expenses of such a testing program would lessen the financial resources available for other congressionally-mandated MCSAP programs, i.e., roadside vehicle safety inspections.

We have decided not to adopt the MCSAP option at this time for several reasons. On October 28, 1993, President Clinton issued Executive Order 12875, "Enhancing the Intergovernmental Partnership," which prohibits executive departments from promulgating regulations that impose an unfunded

mandate on State, local and tribal governments, unless the mandate is required by statute, direct costs are funded by the Federal Government, or the executive department justifies the need for the mandate to the Office of Management and Budget (OMB) after appropriate consultation with the affected governments. The costs of State-operated random alcohol testing would exceed the total annual MCSAP funding allocation of \$65 million. With current limited budgetary resources, it is unlikely that the MCSAP program or any other Federal program will obtain additional appropriations to fund State testing. Legislation would be needed to collect user fees and use those fees to cover any additional, necessary MCSAP funding. Moreover, the MCSAP option could never completely replace employer-based programs; it could cover only three of the types of testing (random, reasonable suspicion and post-accident) and only on certain roads. Furthermore, in some States, the MCSAP program is directed through agencies other than the police, who would be the likely candidates to do the testing. Before it could be implemented, this option would require numerous changes to existing State statutes or constitutions to permit State and local officials to test without probable cause.

Multi-Agency Coverage

Multi-Agency Coverage In some transportation industries, a significant percentage of employees are subject to the testing rules of more than one DOT OA; some are subject to the testing rules of more than one Federal agency (e.g., employee drivers covered by the Department of Energy (DOE) may also be covered by FHWA). This is one reason we have tried to make the DOT OA rules as uniform as possible (and why we have also consulted closely with other Federal agencies). Where it does not compromise the effectiveness of the testing program or other requirements, one DOT OA will defer to another or recognize the validity of the other's requirements. For example, FHWA defers to FTA for CDL holders employed by FTA grantees, and FTA defers to FRA for grantees that are part of the general railroad system of transportation.

There are different situations in which multi-agency coverage can occur:

(1) An employee may perform different modal functions for the same employer. For example, an employee may act as both a pipeline inspector and a truck driver for a single employer, activities regulated by RSPA and FHWA, respectively. Such an employee would be designated by the employer as

either a pipeline worker or driver for purposes of random testing based on which function he or she performs the majority of the time. The employee would be subject to reasonable suspicion and post-accident testing under RSPA or FHWA rules while performing either pipeline or driving functions.

(2) An employee may have two employers. For example, an employee may fly for one employer and drive for another. That employee will be subject to two OA random testing requirements and will generally be in two different pools. As discussed above, however, the employee can be covered by one random testing pool, e.g., one run by a consortium; in both situations, the employee will be subject to random testing in either job at the appropriate industry rate.

The rules require that employees cease safety-sensitive functions in every mode of transportation, once determined to be in violation of any one of the OA rules. We note that the Act clearly prohibits the performance of safety-sensitive functions in the aviation, rail, motor carrier, or transit industries by an employee who has used alcohol in violation of any law or any Federal regulation.

We also have continued to consult with other Federal agencies that are considering developing similar programs during this rulemaking proceeding in an attempt to make Federal government rules as consistent as possible.

International Issues

The Act mandates that the requirements for pre-employment, reasonable suspicion, random and post-accident tests for alcohol (and drugs) be applied to foreign operators in the aviation, rail and motor carrier industries to the extent those requirements are consistent with our international obligations. We must also "take into consideration any applicable laws and regulations of foreign countries." Because of the many questions raised about the implementation of this statutory mandate, we issued advance notices of proposed rulemaking on these issues. Published elsewhere in today's **Federal Register** are FHWA, and FAA NPRMs that propose to cover foreign operators in the U.S., but would defer implementation until January 1, 1996. During this period, we will be working through international organizations or bilateral agreements to achieve programs comparable to DOT's for alcohol and drugs; if we are unsuccessful at making progress, the

rules will go into effect. Because in their very limited foreign operations in the U.S., foreign railroad employers already are complying with FRA's existing alcohol and drug testing requirements, the FRA has published a notice withdrawing its advance notice of proposed rulemaking elsewhere in today's *Federal Register*.

Regulatory Analyses and Notices

General

Each of the OA preambles separately addresses a number of administrative matters concerning compliance with administrative requirements in statutes, executive orders and Departmental policies and procedures. Readers should refer to the individual OA rules for statements specific to each rule. This common preamble and all the associated rulemakings published in today's *Federal Register* have been classified as significant under Executive Order 12866 and the Department's regulatory policies and procedures and have been reviewed by the Office of Management and Budget.

Paperwork Reduction Act

The proposed information collection requirements contained in the notices of proposed rulemaking were reviewed by the Office of Management and Budget (OMB) under section 3504(H) of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Revisions of the information collection requirements contained in the final rules have been submitted to OMB for final approval. A *Federal Register* notice will be published when that approval has been obtained.

Appendix A to Common Preamble—Bibliography

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Issued on January 25, 1994, in Washington, DC.

Federico Peña,
Secretary of Transportation.

David R. Hinson,
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Rodney E. Slater,
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Tuesday
February 15, 1994

Part III

Department of Transportation

Office of the Secretary
National Highway Traffic Safety
Administration

49 CFR Part 40

Procedures for Transportation Workplace
Drug and Alcohol Testing Programs and
Proposed Model Specifications for
Screening Devices To Measure Alcohol in
Bodily Fluids; Final Rule, Proposed Rule,
Notice

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket 48513]

RIN 2105-AB95

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: Under the Omnibus Transportation Employee Testing Act of 1991, the Department of Transportation is required to implement alcohol testing programs in various transportation industries. This rule establishes uniform testing procedures that would be used by all Department of Transportation operating administrations conducting alcohol testing programs under the Act or conducting alcohol testing programs modeled on those required by the Act. This rule also implements changes required by the statute in the Department's drug testing procedures.

DATES: Effective Dates: This rule is effective March 17, 1994, except § 40.25(f)(10)(i)(B), which is effective August 15, 1994. Compliance Date: Compliance with § 40.25(f)(10)(i)(B) is authorized beginning March 17, 1994.

FOR FURTHER INFORMATION CONTACT: Donna Smith, Acting Director, Department of Transportation Office of Drug Enforcement and Program Compliance, 400 7th Street, SW., Washington DC, 20590, room 9404, 202-366-3784; or Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, 400 7th Street, SW., room 10424, 202-366-9306.

SUPPLEMENTARY INFORMATION:

Background

The Omnibus Transportation Employee Testing Act of 1991, enacted October 28, 1991, directed significant changes in the Department of Transportation's substance abuse-related programs for most transportation industries that the Department regulates. These changes are discussed in detail in the Common Preamble published in today's *Federal Register*. With respect to drug testing procedures, the Act added a requirement for using the "split sample" approach to testing, which Congress believed would provide an additional safeguard for employees. The Act also imposes a variety of requirements for alcohol testing procedures, which this regulation also implements. The Coast Guard is not

amending its existing alcohol testing regulations (33 CFR part 95 and 46 CFR part 4), and will continue to use separate procedures for that testing.

The Department's drug testing procedures, 49 CFR part 40, have governed drug testing under all six operating administration drug testing rules since 1988. Likewise, this rule governs alcohol testing procedures for the five modes affected (the Coast Guard is not covered by the alcohol testing procedures of this part). Under the rule, the existing drug testing procedures become a separate subpart of the regulation, and we are adding new subpart containing the alcohol testing procedures.

Having all the Department's uniform drug and alcohol testing procedures in a single regulation will simplify compliance for covered parties and avoid confusion by permitting all parties to look to one source for information on these issues. This should be particularly helpful to those employers who have employees covered by more than one DOT operating administration. However, employers regulated solely by the Coast Guard should continue to refer to 33 CFR part 95 and 46 CFR part 4 for alcohol testing requirements and procedures.

The Department published the Notice of Proposed Rulemaking (NPRM) for this rule on December 15, 1992, at the same time as the operating administrations (OAs) published their proposed alcohol and, in some cases, drug testing rules. We received over 250 comments to the part 40 docket. In addition, the OAs' dockets received some comments on the testing procedure issues raised by the part 40 NPRM. The Department considered all these comments.

Comments and Responses

Split Sample Procedures for Drug Testing

This discussion concerns how we will carry out a statutory requirement to use the "split sample" method for collecting and analyzing urine samples for purposes of the Department's drug testing program. The Act requires split samples to be used for testing under the Federal Highway Administration (FHWA), Federal Aviation Administration (FAA), Federal Transit Administration (FTA), and Federal Railroad Administration (FRA) rules.

Mandatory Use of Split Sample Method

The NPRM proposed to implement the statutory requirement for split samples in drug testing by making mandatory the optional split sample

procedure in the existing part 40. The procedure would remain optional under the Research and Special Programs Administration (RSPA) and Coast Guard drug testing rules, which are not affected by the Act. Several commenters wanted the split sample procedure to remain optional in all modes. Because the statute requires the use of split samples in the four OAs mentioned above, the Department cannot adopt this comment. In order to give employers time to prepare to use the split sample collection method, the rule does not require affected employers to begin using this method until 6 months from the date of this rule's publication. Employers, who under the existing rule have the option of using this approach, may begin using the split sample method at any time.

Sample Volume

The NPRM proposed that the total amount of urine collected be 45 ml (30 ml for the primary specimen and 15 ml for the split specimen). The existing rule calls for a 60 ml collection; the Department believed that this was a greater quantity than is needed. Eighteen comments supported the NPRM proposal; two commenters opposed the proposal, one of whom supported collecting 60 ml each for the primary and split specimens. Based on information about laboratory testing needs gained over the course of four years of implementing a drug testing program, the Department is persuaded that 45 ml (30 ml for the primary specimen and 15 ml for the split specimen) is sufficient. This reduction from the current 60 ml minimum should also reduce "shy bladder" situations in which a test is canceled for lack of sufficient specimen volume.

Time Period for Requesting Test of Split Specimen

Another subject of interest to commenters was the time frame in which employees could request a test of a split specimen. The NPRM proposed a 72-hour period, following the employee's being informed of a verified positive test, during which he or she could request a test of the split specimen. Twenty commenters favored this approach, saying that this period was sufficient to allow an employee to make a choice about whether to request the test of the split specimen. Some of these commenters also asserted that allowing the much longer times permitted under some OA regulations (e.g., 60 days) could lead to tests of deteriorated samples and unreasonably postpone employer disciplinary actions. Seven commenters suggested a longer

time frame (e.g., a week, 20 days, 30 days, or 60 days). One of these comments asserted that employees needed a longer time to become aware of their rights, study their options, and seek representation. Three commenters favored a uniform time frame applicable to all OA rules, while one favored allowing each OA to set its own time frame. One commenter asked whether medical review officers (MROs) were required to inform employees of the time period available to request a test of a split specimen.

The Department will adopt, on a uniform basis, the 72-hour time period. The Act requires the Department's procedures to provide for a test of the split specimen "if the individual requests the independent test within 3 days of being advised of the results of the confirmation test." To comply with the statute, the Department is not required to provide a time period longer than 72 hours.

Moreover, the Department has not seen a persuasive rationale for permitting a longer time period. Nothing prevents an employee who is told of a verified positive test from deciding in a very short time to seek a test of the split specimen. For example, some employees testing positive admit that they used drugs. Such employees may well not believe that testing the split specimen is necessary. If the employee concedes that the test was accurate, but contends that the MRO should have verified the test negative based on information concerning legitimate use of a drug, the employee is likely to seek redress other than a test of the split specimen. If, on the other hand, the employee is adamant that he or she never used a prohibited substance, or believes that the laboratory erred, the employee may well seek a test of the split specimen. None of these decisions on the employee's part need take more than 72 hours. Decisions concerning legal options, representation etc. can be made in the time frames appropriate to the processes involved: the decision on whether to seek a test of a split specimen need not wait on a decision about whether or how to make use of a grievance procedure, for example.

By saying that the 72-hour time period for requesting a test of the split specimen is a uniform requirement, we mean that any time an employee makes a request for a split specimen test within 72 hours of being informed of a verified positive test, the split specimen must be tested. Except in the limited circumstances discussed below, employers or MROs are not required by part 40 to provide for a test of a split specimen if the employee makes the

request more than 72 hours after being informed of a verified positive test. There is no information in the rulemaking record to support the need of employees in any particular industry for a longer time period. Nothing in this provision prohibits an employer from voluntarily (e.g., as part of a labor-management agreement) honoring a request for a test of a split specimen made after 72 hours.

The suggestion that MROs inform employees of this time period is a good one. To make the 72-hour period for making a choice on testing a split specimen meaningful, it is necessary to ensure that the employee knows about the timeframe. For this reason, we have added to the final rule a requirement that the MRO notify each employee about this choice. We have inserted parallel language concerning requests for the reanalysis of the primary specimen in situations (i.e., under the Coast Guard and RSPA drug rules) where the split sample collection method is not used.

Under the final rule, when the MRO tells the employee that he or she has a confirmed positive test, the MRO must also tell the employee that he or she will have 72 hours following notice of a verified positive test in which to request a test of the split specimen. This notification is required in all cases of confirmed positive laboratory results, except in those situations in which an employee has effectively waived the opportunity to talk to the MRO. The 72-hour clock does not start to run until the time when the employee is notified, whether by the MRO or the employer, that the test result is a verified positive.

The employee is not required to wait until after a verified positive test in order to request an analysis of the split specimen. An employee could, if he or she chose, ask the MRO at the time of the notification of a confirmed positive test to initiate the test of the split specimen. The MRO would satisfy this request. The verification process would continue, and the MRO would notify the employer of the verified result in the usual way. The verification and notification processes would not be on hold pending the result of the analysis of the split specimen. Such a delay in removing from performance of a safety-sensitive function an individual with a verified positive test could not be justified on safety grounds. Once a test is verified as positive, the employee must be removed from safety-sensitive functions. The employee may not again perform safety-sensitive duties until he or she has met the conditions of the applicable operating administration rule

for return to duty, pending the result of the test of the split specimen.

In any situation in which the MRO does not personally notify the employee of a verified positive test, we advise the MRO, upon receipt of a request from an employee to test the split specimen, to contact the employer or other party for verification of the time the employee was notified of the verified positive test. This should help to avoid potential questions about whether the employee has made a timely request.

In addition, to ensure that employees are not unfairly deprived of the opportunity to request a test of the split specimen, the Department is adding a provision to allow an employee who fails to request this test within 72 hours to present information to the MRO that the failure to make a timely request was caused by circumstances beyond the employee's control. This provision is similar to one in the existing rule concerning an employee's opportunity to convince the MRO that there was a good reason for the employee's failure to contact the MRO for verification purposes (see § 40.33(c)(6)). If the employee persuades the MRO, the MRO would initiate a test of split specimen, even though the employee's request had been made after the 72-hour period ended.

Number of Collection Containers

With respect to the collection itself, the NPRM proposed that the employee provide the specimen into a collection container, which would, in most cases, be subdivided and poured into two separate specimen bottles. One commenter favored the proposed approach; six others said that a two-container, rather than three-container approach, made more sense. That is, in all situations—not just unusual situations, as the NPRM proposed—the employee should urinate into a specimen bottle, which would become one specimen. The collection site person would then pour an amount of the urine from that bottle into a second bottle, which would become the other specimen. Commenters said this approach would save time and money.

The Department believes that these comments have merit, and the final rule permits either approach. The employer could use a collection container with the specimen subdivided and poured into two specimen bottles. Alternatively, the employer could use a specimen bottle capable of holding at least 60 ml, into which the employer would urinate. The specimen would then be subdivided, with 30 ml being poured into a second specimen bottle, which becomes the primary specimen

for testing purposes. The original specimen bottle, into which the employee had urinated, would become the split specimen.

This latter point may seem counter-intuitive, but there is a reason for it. We want to make sure that there is a 30 ml primary specimen. Pouring 30 ml of the void into the second specimen bottle insures that this will be the case. If the instructions were to pour 15 ml of the void into the second bottle, to be used for the split specimen, the primary specimen might wind up with less than 30 ml of urine if the collection site person overpoured. Laboratories have informed the Department that they intend to provide only 60 ml bottles to collection sites, because of the economies of mass producing a single size container and to avoid confusion by collection site personnel. For this reason, the final rule's procedure should not result in extra costs.

Storage of Split Specimens

Three commenters recommended that employers be authorized to store split specimens at the collection site rather than send them to the laboratory, in order to reduce shipping costs. The Department is not adopting this suggestion. Generally, laboratories have better, more secure storage facilities than many collection sites. The chances of loss, deterioration, tampering, etc. of a specimen are likely to increase in non-laboratory locations. A uniform procedure for storage and re-shipment of split specimens is likely to reduce opportunities for error in the system. The rule also addresses the issue of how long the split specimen should remain in storage. As noted above, the employee must notify the MRO within 72 hours of being informed of a verified positive test to trigger a requirement for a test of the split specimen. Consequently, it is not necessary for the laboratory to retain the split specimen for a prolonged period. In the Department's view, it is sufficient to require the split specimen to be stored 60 days from the date it arrives at the laboratory, if a request for testing it has not been received. (The primary specimen would remain in storage for one year, as under the existing rule.)

Choice of Alcohol Testing Methods and Devices

NPRM Proposal

The NPRM for alcohol testing procedures proposed that both the initial and confirmation tests would be done on an evidential breath testing device (EBT). An EBT is a breath testing device that is on the National Highway

Traffic Safety Administration's (NHTSA) Conforming Products List (CPL), a list of breath testing devices that NHTSA has approved for use by law enforcement agencies in drunk driving cases. In addition, the EBTs would have to print out results and assign a sequential number to tests, to ensure that test results were preserved in a way that minimized the chances for human error or collusion (e.g., the disregarding of an initial positive test by an employer who did not want to lose an employee's services).

The NPRM also proposed training requirements for breath alcohol technicians (BATs), who would administer the tests, and maintenance and calibration requirements for EBTs. In requiring EBTs for all testing, DOT proposed that other testing methods—blood, saliva, urine, non-evidential breath, performance testing—could not be used for either screening or confirmation tests. In summary, the Department made this proposal because EBTs are a well-established, reliable, and accurate testing method; EBTs are minimally intrusive; EBTs can provide an on-the-spot result that allows employers to take action that prevents potential safety risks; and EBTs can produce a printed record of the test result that will prevent disputes about the accuracy and integrity of the testing process.

Comments

Overview

This proposal generated more comments than any other feature of the NPRM. Approximately 190 of the comments to part 40 addressed some aspect of testing methodology. These comments came from a variety of sources, including employers in all the industries covered by the proposed regulations, unions, laboratories, manufacturers of testing equipment and products, and consortia and third-party testing service providers. The most consistent theme among comments on this subject was a desire for greater flexibility in the choice of testing methodology than the NPRM proposed.

Support for NPRM Proposal

Twenty-six comments, representing employers in several industries, unions, third-party testing services, manufacturers of breath testing equipment, state police agencies, and the National Transportation Safety Board, supported the NPRM proposal. They cited as reasons for their support the non-invasiveness of breath testing, its long acceptance by courts and employees, its provision of a

quantitative readout, simplicity compared to blood or urine testing, and the relatively low operating costs involved. Some of these commenters qualified their support of the NPRM proposal by saying that breath testing, while a good method, should be one of an array of options available to employers, or required only for certain types of testing (e.g., pre-employment and random) where the employer has control over the time and place of testing.

Concerns About Cost of NPRM Proposal

Eighty commenters, representing principally employers in all the regulated industries, third-party testing service providers, and manufacturers of other testing devices that compete with EBTs, said using EBTs for both screening and confirmation tests was too expensive. They quoted capital costs per EBT between \$2-10 thousand (some EBT manufacturers who commented agreed with the lower end of this range). This cost would be multiplied, they believe, by a need to obtain EBTs for all the locations in which employers operate. For example, a trucking association cited a motor carrier that would have to buy an EBT for each of its 600 locations, at an estimated cost of \$1.2 million. In addition, there would be BAT training, maintenance, and calibration costs. Commenters who talked in cost per test terms cited estimates of between \$20-100 per test, which they said was much higher than for competing methods. Railroad industry employers (who now use breath testing for alcohol) said that, to reduce capital costs, EBTs should not be required to have the sequential numbering and printout capabilities proposed in the NPRM (which they said would add \$1500 to the cost of an EBT).

Concerns About Difficulty in Implementing NPRM Proposal

Some commenters feared that there would be insufficient numbers of EBTs, BATs, and testing sites available to implement the proposal. There would be a rapid expansion of the need for EBTs (one commenter estimated a 3000-4000 percent increase in the market) that manufacturers may be unable to fulfill, as well as a rapid training need for thousands of BATs that would take substantial time to meet. Seventeen commenters (including a number of third-party service providers and employers) said that the cost of obtaining EBTs and training BATs, the unfamiliarity of many third-party testing sites with breath testing, and liability concerns would deter many potential third-party service providers from

participating. This would particularly be a problem in small towns and rural areas, where the low volume of testing would make the needed investment too costly.

Concern About Confrontations

Twenty-eight commenters (principally third-party service providers and employers) expressed concern about the possibility of confrontations between BATs and employees. These confrontations would occur, commenters said, because the BAT—not an employer representative with supervisory authority over the employee—would be the messenger of bad news about a test result. Several commenters cited the image of a 90-pound female BAT having to deal with an angry (and perhaps intoxicated) 300-pound truck driver who had just been told he had failed an alcohol test.

Other Comments About NPRM Proposal

Commenters expressed other concerns about the EBT-EBT approach. Some found the process too time-consuming. Others pointed out that the collection site is commonly recognized as the weak point of the drug testing process, and that conducting the alcohol testing process there increased the chance of error. Other comments said that there were too many opportunities for human and mechanical error in the breath testing process, which, together with what they regarded as the unreliability of EBTs at low alcohol concentrations, created numerous opportunities for litigation. Some commenters also said that, if all screening and confirmation testing were done on EBTs, the two tests should be run on different machines.

Legal Issues

Several commenters raised legal challenges to the proposal. Nine commenters (primarily manufacturers of competing devices and unions) said that the statute requires split samples (i.e., the subdivision and retention of a portion of a sample for an additional test at a laboratory as a safeguard for the accuracy of the process) in all cases. Generally, EBTs do not retain breath samples. Therefore, these comments said, methods that permitted split samples (e.g., blood, urine, saliva) must be used. Thirty-one comments said that the statute contemplated the use of different methods for the screening and confirmation test, respectively. Eleven comments said that, since the results of EBT tests would be used to refer persons for rehabilitation or treatment, they would be considered medical devices subject to Department of Health and Human Services (DHHS) regulation.

Since DHHS had not approved EBTs as medical devices, their use could be blocked.

Desire for More Flexibility

Seventy-five commenters (representing a wide variety of equipment manufacturers, employers, and third-party service providers) favored allowing employers to choose the best testing method for them. In addition to the virtue of flexibility, this approach would permit each employer to choose the most cost-effective method of compliance in its own circumstances.

Most of these commenters appeared to favor testing methods that would use two different testing methods (e.g., non-evidential breath or saliva screening test, blood test for confirmation). Ten commenters disagreed on this point, saying that non-evidential screening tests should never be permitted. Their primary concern was about the accuracy of these testing methods. Several commenters who favored using non-evidential screening tests conceded that it would probably be necessary to suspend an employee's performance of safety sensitive functions pending a confirmation test of a positive non-evidential screening test. Most commenters who addressed confirmation procedures in a two-method system said that confirmation tests (of whatever body fluid) should be done on GC (gas chromatography, the same highly accurate method used for confirmation tests under the drug testing program).

Specific Comments on Other Testing Methods

Non-Evidential Breath Testing Devices

(e.g., tubes filled with materials that turn a certain color when alcohol-laden breath is blown into them or small, hand-held electronic devices that register the presence or absence of alcohol concentration in breath)

Twenty-nine commenters, including a variety of employers and manufacturers of the devices, supported using non-evidential breath testing devices. Most commenters cited cost (estimated at between \$90–\$550 for various models of non-evidential breath testing machines, and about \$2–4 each for disposable devices) and convenience as reasons. A few opponents of non-evidential breath testing devices said their accuracy was questionable, both with respect to false positives and false negatives.

Saliva Testing

(i.e., a device which registers a particular alcohol concentration when a

swab with saliva from the employee's mouth is inserted into it)

Forty-five commenters favored the use of saliva testing. These commenters included a variety of employers, third-party service providers, equipment manufacturers, and others. Commenters claimed several advantages for use of screening saliva tests: modest cost (estimated at between \$5–20 per test); simplicity of use, little need for training; existing "approvals" from NHTSA and Food and Drug Administration (FDA) for some devices (though in contexts other than a workplace testing program); non-invasive nature of the devices; sufficient accuracy for screening tests. Two commenters also said that, while it was most typical to use blood testing for confirmation after a saliva screen, saliva specimens could also be used for confirmation, as laboratories could run a gas chromatography analysis on saliva.

A few commenters expressed concerns about saliva testing devices. A union provided data that it said showed that saliva devices had a mixed record for accuracy. Other commenters said saliva remained an unproven method, that saliva devices were not ethanol-specific, and that saliva alcohol and blood alcohol results may differ. Proponents of saliva testing devices conceded that chain of custody forms would be needed and that there was no method of automatically generating permanent records of test results that positively identified a particular employee with a particular result. They said that keeping paper records was adequate for this purpose, however.

Blood Testing

Forty-eight commenters (again representing a variety of employers, plus third-party providers, laboratories and others) favored allowing the use of blood testing as a confirmation test method. The advantages cited for this method included well-established scientific and legal acceptance for accuracy, the availability almost anywhere of technicians trained in drawing blood, and utility for post-accident testing on employees who are unconscious. Some of these commenters said that, while blood testing is admittedly more invasive than other methods, employees accept it because of its reputation for accuracy. Also, they said, the low expected positive rates on screening tests will mean that few blood confirmation tests would have to be performed. Commenters estimated costs to be in the \$20–60 range per test.

Seven commenters opposed the use of blood testing, primarily on the ground that it is too invasive. In addition, a few commenters said that DHHS or DOT

would have to develop laboratory certification standards for blood testing. Some comments said that employees might have to be required to "stand down" during the interval between the blood collection and the return of the test result from the laboratory.

Urine Testing

Eight commenters favored allowing the use of urine testing, including some employers who now use this approach to their satisfaction and laboratories that do urine testing. One advantage cited for this approach is that alcohol could simply be added to the list of substances for which urine samples taken for drug testing are tested, at a low incremental cost. Commenters said that DOT or DHHS should develop laboratory certification procedures and cutoff levels. Some commenters also noted that detailed collection procedures would have to be developed, since urine testing for alcohol is more complicated than urine testing for drugs (e.g., two voids, twenty minutes apart, are recommended to measure alcohol concentration in urine).

Performance Testing

Five commenters, most of whom were manufacturers of the devices, supported the use of performance tests for the screening or screening test. (A performance test does not measure alcohol concentration; it measures deviations from a personal norm of reaction time, motor coordination, etc.) One commenter opposed performance testing devices as inappropriate for this program.

Responses to Comments on Testing Methods

Legal Issues

The Act provides, with respect to confirmation testing, that all tests * * * shall be confirmed by a scientifically recognized method of testing capable of providing quantitative data regarding alcohol * * *

Some comments asserted that this provision requires that a different testing method be used for the screen and confirmation tests, respectively. The statute says no such thing, stating only that the confirmation test must use a "scientifically recognized" method that can provide "quantitative data" regarding alcohol. As long as the method of confirmation meets these criteria, the statutory requirement is satisfied. Breath testing is scientifically and legally recognized as a method for accurately testing alcohol concentration, and devices meeting the Department's requirements provide quantitative data.

(Blood testing, of course, also meets the statutory criteria.)

The ability of a method of confirmation testing to pass these statutory tests is not dependent on the choice of a method of screening testing. Testing of breath for confirmation, as provided in this rule, is equally valid under the statute whether evidential breath testing, non-evidential breath testing, or saliva is used for the screening test. Testing of blood for confirmation is equally valid under the statute whether blood, breath, saliva or urine is used for the screening test. All that matters is that the confirmation testing method meet the statutory criteria in its own right.

With respect to split samples, the Act requires the Department's regulations to provide that each specimen sample be subdivided * * * and that a portion thereof be retained in a secure manner to prevent the possibility of tampering, so that in the event the individual's confirmation tests results are positive the individual has an opportunity to have the retained portion assayed by a confirmation test done independently at a second certified laboratory if the individual requests the independent test within 3 days after being advised of the result of the confirmation test * * *

Some commenters asserted that this language should be read to require that split samples be used in all alcohol testing, with the implication that a method that did not permit the use of split samples could not be used. Since most EBTs—including those proposed by the Department in the NPRM—do not retain a sample that could theoretically be subdivided and preserved for testing of a split specimen, some of these commenters asserted not only that blood or other liquid-based testing methods were required, but that breath testing was prohibited.

This interpretation is flatly contrary to the statute, which specifically contemplates the use of breath testing (see, e.g., sec. 3(a) of the Act, adding section 614(d)(6) to the Federal Aviation Act). Breath testing is a well-recognized form of alcohol testing, and there is no evidence that Congress had any intention of prohibiting its use, either indirectly by requiring split samples or otherwise. The legislative history makes clear that the Senate sponsors of the legislation intended that breath testing be used and that split samples were not mandated for breath testing. In the floor debate, during a colloquy between Senators Danforth and Hollings, Senator Hollings stated

(t)here are also requirements for split samples, primarily included in the legislation

to allow urine samples to be retested. DOT would have the authority to determine that blood samples should be similarly handled. This specific requirement is not relevant in the case of breath testing for alcohol, but DOT is directed by this legislation to provide necessary safeguards in this area to ensure the validity of test results.

137 Cong. Rec S 14764, 14770.

There is also internal evidence in the wording of the statutory provision that supports the reasonable interpretation that the split sample requirement is intended to apply to liquid body fluids like urine and blood, but not to breath. The statute uses the word "samples" in ways that refer primarily to samples of liquid body fluids. For example, section 614(d)(1) of the amended Federal Aviation Act refers to the need for "privacy in the collection of specimen samples." Privacy is very important with respect to collection of urine samples for drug testing. Because elimination functions are not involved, privacy is not as important in breath collections. In paragraph (d)(6) of the same section, the statute refers to detecting and quantifying "alcohol in breath and body fluid samples, including urine and blood." In this language, the phrase "including urine and blood" is best understood as modifying "body fluid samples," as opposed to "breath." Given the way that the term "sample" is used in these portions of the statute, the use in paragraph (d)(5) of "sample" should also be used to refer to liquid body fluid samples (i.e., urine and blood). When this paragraph speaks of the "specimen sample be[ing] subdivided," then, it is imposing a split sample requirement on blood and urine, not on breath.

Some commenters argued that the language mentioned above from paragraph (d)(6), requiring the Department to "ensure appropriate safeguards for testing to detect and quantify alcohol in breath and body fluid samples, including urine and blood * * *," creates a right for employees to have a screening test confirmed by blood testing. This language, on its face, does not create such a requirement, since it does not specify any particular sort of test for either screening or confirmation purposes. There is ambiguous legislative history on the point, with the Senate report on the Act saying both that "an employee testing positive for alcohol using a specimen other than blood shall be entitled, at that employees [sic] option, to a blood test" and that "the Committee has not specified the type of test to be used in either the screening or confirmation test." Given that the statute does not explicitly require blood

testing for confirmation, and that the portion of the statute that mandates confirmation testing requires only a "scientifically recognized" confirmation test that can produce "quantitative data" (criteria that breath testing clearly meets), the Department does not believe it would be reasonable to view this ambiguous legislative history as a mandate for the availability of blood confirmation testing in all cases.

The Department does not believe that regulations of the Food and Drug Administration (FDA) would interfere with the implementation of breath testing under this rule. FDA does regulate the safety, labeling, etc. of medical devices. It is our understanding that FDA may be considering initiatives to regulate EBTs used as medical devices in medical settings. FDA does not, however, regulate or certify the precision or accuracy of EBTs that are currently used for law enforcement purposes or that would be used under the DOT alcohol testing program. (These would not be viewed as medical devices used in medical settings.) We believe that current FDA rules are, and future FDA rules would be, consistent with NHTSA certification of EBTs.

Flexibility and Cost

Many commenters made flexibility in testing methods a high priority. The Department agrees that flexibility is desirable. However, the Department also believes that any testing system should meet a series of criteria, each of which is necessary to execute the statute faithfully and to ensure that the safety and accuracy goals of the program are met. The Department cannot emphasize too strongly the importance of ensuring accuracy and reliability of testing devices and methods, at both the screening and confirmation test stages. This is needed, among other reasons, to protect employees from even temporarily being identified as misusers of alcohol. In the context of drug testing litigation, the courts, in upholding the Department's program, relied to a substantial extent on the reliability and accuracy safeguards in that program.

Within these constraints, our objective is to provide maximum flexibility and minimum cost. The Department's criteria for carrying out its objectives in this area are the following:

- As required by the statute, the method used for confirmation should be scientifically recognized and able to produce a quantitative result. The method should meet NHTSA Conforming Products List (CPL) standards at 0.02 and higher alcohol concentrations.

- The confirmation method should be alcohol-specific (i.e., does not produce a reading for acetone).

- The confirmation method should generally provide documentation of quality control/calibration and be admissible as forensic evidence in administrative proceedings.

- The testing method used for confirmation should provide a result at the time and place of the test, so that an employee whose continued performance of a safety sensitive function may present a safety risk can be removed from performing that function.

- The testing method used for the screening test should minimize the occurrence of false positives and false negatives and should meet stringent standards for precision and accuracy (e.g., ± 0.005 at 0.02 alcohol concentration).

- The testing method used for screening tests should provide a result at the time and place of the test and be specific for measuring alcohol concentration.

- The testing methods used for confirmation tests should provide a printed, permanent record of the test number and test result, in order to avoid uncertainty about whether this employee took this test with this result. The testing methods used for screening tests should provide either this kind of record or be used in conjunction with procedures that provide a record of the test result linked to the individual tested through some form of permanent documentation. The purpose of this criterion is to prevent collusion and cheating.

- The testing methods used for screening and confirmation tests should, as a policy matter, be as non-invasive as possible.

At the present time, only evidential breath testing methods meet all these criteria for screening and confirmation tests. Applying these criteria strictly would result in a final rule that, like the NPRM, permitted only evidential breath testing for both tests. The points made by commenters favoring the NPRM approach further support using evidential breath testing for both tests.

The Department, to achieve a reasonable balance between the legal and policy goals on which the criteria are based and commenters' desire for greater flexibility, is modifying the approach proposed in the NPRM. First, the final rule will permit EBTs that are on the NHTSA CPL, but that do not meet the additional requirements for confirmation EBTs (e.g., sequential numbering and print-out capability), to be used for any screening test. While these EBTs may be used for screening

tests at this time, because NHTSA has determined them to meet appropriate accuracy and precision standards, non-evidential breath screening devices (e.g., "breath tubes") may not be used at this time.

Second, in an NPRM published in today's *Federal Register*, the Department will propose to permit blood testing to be used in limited circumstances. In the case of a reasonable suspicion test or a post-accident test, where an EBT meeting the requirements of part 40 is not readily available, the employer could use blood testing for the confirmation test. Blood alcohol testing would also be available as an option in "shy lung" situations. This NPRM also proposes blood testing procedures to be used in these circumstances. The rationale for allowing this limited use of blood testing is discussed in the preamble to the NPRM.

Third, the Department is also publishing in today's *Federal Register* a notice proposing to adopt criteria and procedures that would permit additional alcohol screening devices to be used for screening tests in the program. This proposal would be intended to result in the adoption of model specifications for a conforming products list for alcohol screening devices. Under this proposal, manufacturers of devices could submit their products to DOT for evaluation and, if their devices met the model specifications, the Department would authorize their use as screening devices in DOT-mandated alcohol testing. This approach will permit greater flexibility in the use of screening devices that are not now appropriate for use, including those supported by their manufacturers and others in comments to the part 40 docket, if they are able to meet DOT model specifications.

With respect to costs, commenters had three basic concerns. First, commenters believed that EBTs meeting all the NPRM's requirements would be too expensive. Some commenters believed that adding features such as a sequential numbering and printout capability would add considerably to the cost of the devices. The Department's information, included in our regulatory evaluations, and based on data obtained from manufacturers, suggests that the list price per unit of an EBT meeting all the NPRM criteria for use in confirmation tests is about \$2000. (There are some indications that prices may be lower for purchases in quantity.) There are other EBTs on the CPL, available under the final rule to be used for screening tests, that list for about

\$1000, again with the possibility of lower prices for purchases in quantity.

Because the Department is proposing to permit blood testing in post-accident and reasonable suspicion situations where a breath testing unit is not readily available, the numbers of EBTs that any employer would have to obtain may be reduced significantly from earlier estimates, lowering many commenters' estimated capital costs of the program. This is because employers would not have to provide an EBT at all its work sites against the contingency of a reasonable suspicion or post-accident test happening there, as a number of employers' estimates assumed. Commenters identified having to preposition EBTs at all work sites, even the small and remote ones, as a major cost of compliance with the NPRM (even though the NPRM would not have imposed this requirement). In addition making blood testing available means that the time workers would be held out of service pending a test would be reduced significantly, resulting in further savings. We refer commenters to today's NPRM on blood alcohol testing for further information.

Second, commenters expressed concern about the costs of training personnel and maintaining and calibrating the instruments. While training can be expensive, we believe that these costs are difficult to avoid if the accuracy and integrity of the testing program are to be protected. As other devices are approved under the Department's forthcoming procedures, employers will have the opportunity to determine if use of other methods will reduce their overall costs.

Third, some commenters (especially from the railroad industry) who already use EBTs expressed concern about the costs of the additional features that the NPRM would have required (e.g., sequential numbering capacity, print-out capability). The final rule responds to these concerns by allowing EBTs without these features to be used for screening purposes. A railroad could use its existing EBTs (assuming they are on the NHTSA CPL) for screening tests, while obtaining only as many of the machines with the additional features as it needed for confirmation testing. This would reduce the additional costs that these employers would have to incur.

When the Department issues a broad mandate for employee testing, the overall effect is likely to be the creation of additional opportunities for professionals, manufacturers, and other businesses to serve the markets created by the DOT requirements. These opportunities can fairly be expected to lead to an influx of participants into the

market. There is ample evidence that this has been the case in the Department's drug testing program, and it is reasonable to expect that similar economic opportunities will draw businesses and professionals into the alcohol testing market. The Department believes that this factor is likely to outweigh, by a substantial margin, any deterrent effects on participation in the program related to equipment or training costs, the newness of the procedures, liability, or the willingness of businesses and professionals to participate.

Comments that potential participants would be deterred for these reasons were, for the most part, speculative. Given the market's response to the drug testing rules since 1988, it is fairer to assume that the market's response to the even larger-scale alcohol testing program will not be timid. With respect to the issue of sufficient EBTs being available, the Department has contacted EBT manufacturers, and we do not anticipate any serious shortage of devices as the program begins operation. If, at any time, the Department learns that there are inadequate supplies, the Department could postpone or otherwise modify its rules.

While the image of a large, angry, intoxicated employee confronting a 90-pound female BAT over a positive result is a graphic one, the speculation and spotty anecdotal evidence provided by commenters to back up their concern on this matter is not sufficient to cause the Department to retreat from its position that immediate results are needed. (This concern goes to any testing method that provides an immediate result, not just to breath testing. It might appear even more strongly in a situation in which an individual is told, as the result of a non-evidential screen, that he is to "stand down" and not work for three days while a laboratory test result is obtained.)

The point of getting an immediate result is safety: if an employee, of whatever size, has a higher alcohol concentration than the Department's rules permit, the individual should not be performing a safety-sensitive function. In the interest of safety, we need to stop the individual's performance of that function now, not two or three days later when a laboratory test result becomes available. We also want to prevent the unnecessary cost of holding an employee out of service for two or three days pending laboratory results following a non-evidential screen. BATs are not given the responsibility of taking a driver's keys away. The DOT alcohol testing form includes a statement, to be

signed by the employee, that persons who test positive should not drive or perform other safety-sensitive functions. Employers have a responsibility, as part of their alcohol education for employees, to emphasize that employees must cease performing safety sensitive functions if they test positive.

The Department does not believe that it is necessary to use two separate EBTs in order to have a valid, defensible result. EBTs on the NHTSA CPL are designed for accuracy, and the internal and external calibration checks built into the Department's procedures are sufficient insurance against error. (Where employers choose to use an EBT without the additional features for screening tests, of course, the employer will necessarily use a different machine for the confirmation test.) The Department is convinced that EBTs meeting its requirements are sufficiently accurate and reliable, at the alcohol concentrations that will be tested for, and that excessive invalidations of tests or successful lawsuits or grievances will not occur. Similarly, the likelihood of extensive errors by testing personnel should be diminished by the BAT training requirements.

Manufacturers of alternative testing devices, and some other commenters as well, advocated various other methods of testing, particularly for screening tests. As noted above, the Department intends to take action that could result in decisions to authorize use of other screening devices and to authorize the use of blood testing in some circumstances. The Department has decided not to permit the use of these alternative methods until they can meet the criteria we believe are necessary for accurate testing meeting the requirements of the statute. The following paragraphs summarize the Department's reasons for not permitting the use, at this time, of other testing methods:

Blood Testing

- This is the most invasive form of testing.
- Employees may fear needles or fear infection from improper medical procedures.
- Additional collection procedures, chain of custody procedures, and equipment requirements would be needed, making regulatory requirements more complex.
- Laboratory certification standards and testing protocols would need to be established. As noted in the accompanying NPRM, this poses potentially significant problems even in the limited context in which the Department is proposing to permit the use of blood testing.
- Results would not be available for at least 24 hours, and could take 3-4 days to arrive. Confirmed results would, therefore, not be available at the time the employee was

affected by alcohol, which would reduce the safety benefits of the program.

Urine Testing

- Present laboratory certification standards and testing protocols do not cover urine testing for alcohol. There would have to be additional laboratory certification procedures and testing protocols developed for urine testing.

- Urine testing for alcohol (as distinct from drugs) requires a complex collection process, involving two separate voids with an interval between them. Addition of a preservative to prevent the creation of alcohol by microbial fermentation is also recommended. We would need to add new collection procedures to accommodate these requirements, as well as new training requirements for collection site personnel. These additional procedures would make the collection process more complex and multiply the chances for errors.

- Urine testing is regarded as the least accurate method currently available for determining the amount of alcohol in the body.

- A blood to urine ratio has not been definitively established, making it difficult to equate a urine test result for alcohol to a particular blood or breath alcohol level.

- There are greater costs of employee "downtime," for transporting the employee to a collection site for testing and for the longer collection procedure.

- Testing of urine specimens would have to take place in a laboratory. Results would not be available for at least 24 hours, and could take 3-4 days to arrive. Confirmed results would, therefore, not be available at the time the employee was affected by alcohol, which would reduce the safety benefits of the program.

Saliva Testing

- Especially at low alcohol levels, saliva devices are likely to have a higher rate of false positives and negatives than EBTs on the CPL.

- Some saliva devices do not provide quantitative results.

- Because saliva screening testing devices are disposable, and do not generate a record of the test, ascertaining whether a particular employee took a particular test and had a particular result, or that the test took place at all, would be difficult. (The use of a log book, which helps to address this concern where EBTs without sequential numbering or printout capabilities are used, would be difficult in the case of disposable devices. The log book would accompany the EBT wherever it went, which would not be possible with disposable devices.)

- There are different saliva-based technologies, each requiring the establishment of criteria for accuracy, reliability, etc. Until NHTSA criteria are established for these technologies, it is premature to permit their use in the DOT program.

- If laboratory confirmation methods (e.g., blood) are used in combination with saliva screens, confirmation results would not be available for at least 24 hours, and could take 3-4 days to arrive. Confirmed results would,

therefore, not be available at the time the employee was affected by alcohol, which would reduce the safety benefits of the program. If breath testing confirmation is used, cost savings claimed for the use of disposable devices over the use of breath testing for both screening and confirmation testing would be reduced substantially.

- The Department would have to establish additional procedures, training requirements, quality control requirements, etc. for saliva testing, adding further complexity to the program.

Non-evidential Breath Testing

- Non-evidential breath devices (i.e., disposable devices and others not on the CPL) have a higher rate of false positives and negatives than evidential EBTs.

- Non-evidential breath screening testing devices do not generate a record of the test, so that ascertaining whether a particular employee took a particular test and had a particular result, or that the test took place at all, would be difficult. (The use of a log book, which helps to address this concern where EBTs without sequential numbering or printout capabilities are used, would be difficult in the case of disposable devices. The log book would accompany the EBT wherever it went, which would not be possible with disposable devices.)

- If laboratory confirmation methods (e.g., blood) are used in combination with non-evidential breath screens, confirmation results would not be available for at least 24 hours, and could take 3-4 days to arrive. Confirmed results would, therefore, not be available at the time the employee was affected by alcohol, which would reduce the safety benefits of the program. If breath testing confirmation is used, cost savings claimed for the use of non-evidential devices over the use of evidential breath testing for both screening and confirmation testing would be reduced substantially.

- Non-evidential EBTs on the market appear to vary greatly in type of technology used, quality, and accuracy. Until NHTSA criteria are established for these devices, it is premature to permit their use in the DOT program.

- The Department would have to establish additional procedures, training requirements, quality control requirements, etc. for non-evidential breath testing, adding further complexity to the program.

Performance Testing

- The statute requires testing for alcohol concentration, not diminished performance. A test for performance appears not to meet this statutory requirement.

- Performance tests are very unspecific, which could result in positives caused by a wide variety of things other than alcohol use (e.g., illness, prescription or over-the-counter medication, fatigue, emotional distress). This would lead to many unnecessary confirmation tests and could result in employees being taken off the job while awaiting confirmation test results, adding extra costs for employers and employees.

- The accuracy of many performance testing devices is unproven.

- Many performance testing devices do not generate a record of the test. Ascertaining

whether a particular employee took a particular test and had a particular result, or that the test took place at all, could be difficult.

- Most performance testing devices require the establishment of individual baseline data for each employee, which can be a time-consuming and costly procedure.

- In many systems, performance evaluation must relate to critical job skills, measures of which have not been established for many occupations.

- Performance testing devices or systems on the market appear to vary greatly in quality and accuracy. Until NHTSA criteria are established for these devices, it is premature to permit their use in the DOT program.

- The Department would have to establish additional procedures, training requirements, quality control requirements, etc. for performance testing, adding further complexity to the program.

This discussion is in the context of an extensive, multi-modal testing program, including pre-employment and random testing as well as reasonable suspicion and post-accident testing. Greater protections are needed in such a program, particularly in the absence of procedural protections present in some existing programs that may use non-evidential testing in some circumstances. For example, the Coast Guard post-accident alcohol testing program can involve administrative proceedings in which the employee has the opportunity to challenge test results before a license is revoked or an investigative inquiry at which further evidence could be introduced.

Breath Alcohol Technicians

The NPRM proposed that breath alcohol technicians (BATs) be trained to proficiency in using EBTs and in DOT alcohol testing procedures, using a NHTSA- or state-approved course. The competence of the BAT would have to be documented. Additional (i.e., refresher) training would be required, as needed, to maintain proficiency. An employee's supervisor could not act as the BAT for that employee unless allowed by a DOT rule and no other qualified BAT were available.

Commenters spoke to several provisions of this section. Six commenters favored, and 15 opposed, requiring BATs to be tested to ensure that they are alcohol free (an issue about which the Department had asked a question in the NPRM preamble). A number of the opponents said that this issue should be decided by the BATs' employers. The Department is not adopting this idea, which we believe to be unnecessary to the program.

Forty-nine comments addressed the training and qualification of BATs. All these commenters favored training,

though two mentioned that training might be very costly or difficult, especially for smaller companies. Sixteen comments said that it was not necessary for the regulation to specify that BATs be trained in the pharmacology and physiology of alcohol, about which the NPRM preamble had asked a question. Three commenters took the opposite position. The Department agrees that this training is not needed for BATs, whose training should be focused on the proper operation of testing devices.

Seventeen commenters supported the NPRM approach (including the concept of "training to proficiency"), while two thought the NPRM too vague. Eleven favored specific numbers of hours of training, ranging from 4 to 40, with most of the comments suggesting something between 4 and 8 hours. Two expressed support of recurrent training, one asking for a more specific requirement than the NPRM proposed. The Department believes it is most relevant to ensure the BATs' proficiency. Our goal is to ensure that BATs are able to use the testing devices that they will operate. The Department believes that the best way to make sure that BAT training results in proficient operators is to require that BAT training include a course that is equivalent to the DOT Model Course. Courses followed by state law enforcement agencies and other organizations appear to vary substantially from one another, and may be focused on breath testing in other contexts (e.g., enforcement of DUI laws). NHTSA will review training courses and issue determinations concerning whether they are equivalent to the NHTSA Model Course.

Who should be a BAT? Twenty-two of 23 commenters supported permitting a trained law enforcement officer to act as a BAT. The Department agrees that it is appropriate to authorize trained law enforcement officers to act as BATs (e.g., off-duty officers under contract to an employer), as long as they have been certified by a state or local law enforcement agency. The officers would have to follow DOT testing requirements, including this part, and to be certified to operate the EBT used in the DOT-mandated test. The officers could perform any type of DOT test. Except for the FHWA rule, the OA rules do not permit the substitution of law enforcement tests for tests conducted under DOT procedures.

There was less consensus on the issue of supervisors as BATs. Sixteen commenters favored allowing properly trained supervisors to act as BATs, pointing out that, particularly in reasonable suspicion or post-accident

testing, or at remote sites, supervisors may be the most readily available, or perhaps the only available, trained BATs. Eleven other commenters disagreed, most saying that an employee's supervisor should never be the employee's BAT. These commenters appeared concerned about the appearance or reality of a conflict of interest between the supervisor's managerial role and his objectivity as a BAT. The Department believes that, when possible, someone other than an employer's supervisor must act as a BAT for the employee's test. However, a supervisory BAT is better than no BAT at all. To enable a test to go forward when no other BAT is available in a timely manner, the Department will permit a BAT-trained supervisor to conduct the test. However, if a DOT operating administration regulation prohibits the use of a supervisor in this role (e.g., in reasonable suspicion testing), the supervisor may not act as the BAT even in this circumstance.

EBT Technology

The NPRM required EBTs used for screening and confirmation testing to be on the NHTSA CPL, have the capacity to print out triplicate (or three consecutive identical) results, assign a sequential number to each test, distinguish alcohol from acetone at the 0.02 alcohol concentration level, and have the capability for performing both air blanks and external calibration checks. Commenters addressed a number of points concerning EBT technology.

Some commenters pointed to what they viewed as shortcomings of the CPL itself, particularly that it did not require EBTs to be accurate at the 0.02 level.

This was true of the CPL at the time the NPRMs were issued; however, NHTSA has since modified the model specifications for the CPL to require accuracy and precision at the 0.02 level. Other commenters said that since inclusion on the CPL is based on testing of a prototype, rather than testing of each device, the CPL was an inadequate assurance of accuracy. The final rule does not rely on the CPL alone to ensure accuracy, however. The rule requires there to be a quality assurance plan (QAP) for the instrument as well as air blanks and external calibration checks.

As noted above, a number of commenters criticized the requirement for printing results and sequential numbering capability, saying that these features were unnecessarily costly. Any device on the CPL should be able to be used, one of these commenters said. The final rule responds to these comments by allowing any device on the CPL to be

used for screening tests, with the additional features required only on those machines used for confirmation testing. This should reduce the number of the more expensive models employers will have to obtain.

Some commenters expressed concern about radio frequency interference (RFI) affecting the results of some types of EBTs. The concern is that, in airports and other locations where communications or other electronic equipment is operating, alcohol concentration readings could be distorted. DOT asked manufacturers about this issue, who said that most models of EBTs are shielded to avoid this problem. NHTSA tested three models of EBTs at Washington National Airport and detected no RFI effects on their readings. In addition, NHTSA plans, as part of its process for reviewing quality assurance plans (see discussion below), to have manufacturers establish operational guidelines to avoid RFI problems. The Department believes that it is not necessary to modify the regulatory text to address the commenters' concerns.

Commenters also expressed concern that some EBTs might not be able to distinguish acetone from some alcohols. Commenters also questioned the suitability of the CPL for instruments measuring alcohol concentrations at the 0.02/0.04 levels, since the CPL, at the time of the NPRM, did not address testing at these levels. As noted above, NHTSA has revised the model specifications on which CPL listing of devices is based. The revised specifications address both issues, and EBTs on the CPL will distinguish acetone from alcohol and be accurate at the 0.02/0.04 levels.

A few comments raised other technical issues about the use of EBTs. One issue was the effect of altitude on external calibration standards. Altitude affects gas aerosol standards; NHTSA will address this problem by requiring gas aerosol standards on its CPL for calibration devices to be criterion-referenced for various altitudes.

Another concern was based on the belief that EBTs that display results to only two, rather than three, decimal places would round up. That is, commenters were concerned that someone whose actual alcohol concentration was .036 would be reported as a 0.04, subjecting the individual to heavier sanctions. EBTs on the CPL provide three-digit displays, so this problem does not arise for these devices.

Finally, some commenters expressed concern that defining alcohol concentration in terms of grams of

alcohol per 210 liters of breath was not as accurate as desirable (or as accurate as a blood alcohol reading), because this ratio could vary among individuals. The Department's information is that any variation is very minor and unlikely to affect the results of a breath test or its consequences under these rules. In addition, EBTs are typically calibrated to account for any variation by slightly undercounting alcohol concentration.

Quality Assurance Plans

The NPRM proposed that EBT manufacturers would develop a quality assurance plan (QAP) for each EBT model. The plan would cover such matters as external calibration methods, tolerances and intervals and inspection and maintenance requirements. The manufacturer would have to obtain NHTSA approval of the QAP, and employers would have to comply with it. This compliance includes making external calibration checks as called for in the QAP and taking EBTs out of service if they "flunk" an external calibration check. In addition, the employer would have to ensure that inspection, calibration and maintenance of EBTs is done by the manufacturer, a representative certified by the manufacturer, or an appropriate state agency.

On the basic concept of the QAP, five commenters supported the NPRM's approach, while another eight said that NHTSA, rather than the manufacturer, should establish the standards. Some of the latter commenters appeared concerned that manufacturers may have incentives to establish requirements for their devices that were not optimal. The Department believes that NHTSA approval of the QAPs should be sufficient to ensure that the manufacturer's standards are adequate and that the manufacturers are better positioned than we are to establish model-specific requirements for individual EBTs. For this reason, we are retaining the proposed approach. QAPs would be required for all EBTs on the NHTSA CPL that would be used in DOT-required alcohol testing, whether or not a particular EBT met the additional requirements of this part for use in confirmation testing.

Commenters suggested a wide variety of requirements concerning how frequently an external calibration test must be performed. Some of the ideas included performing such checks before and/or after every test, after every positive test, before, during and after the testing shift, every day, after every five tests, every thirty days, or before disciplinary action is taken on the basis of a positive test. All these comments

respond to a basic point: if an EBT "flunks" an external calibration check, positive tests conducted on that device since the last previous successful external calibration check must be regarded as invalid. This fact provides a strong incentive to employers and BATs to conduct these checks frequently enough to avoid retroactive invalidations of positive tests. In conjunction with the manufacturer's instructions on the QAP, this incentive should be sufficient to induce employers acting in good faith and testers to conduct these checks at appropriate intervals. A generally applicable regulatory requirement for external checks of calibration at a stated interval, on the other hand, would provide less flexibility and might not fit a variety of situations well.

A few commenters suggested specific types of calibration solutions or obtaining such solutions from certified laboratories. Others suggested that the Department establish particular standards for external calibration devices, or allow use of only those external calibration devices that are on the NHTSA CPL. Others suggested particular tolerance standards (e.g., $\pm .005$). The Department does agree that the employers should use external calibration devices that are on the NHTSA CPL, and this requirement has been incorporated into the final rule. The Department does not certify laboratories for production of external calibration solutions, so we could not reasonably require employers to obtain solutions from certified laboratories. For the types of solution that work best with a particular machine, or for the tolerance standard that is most relevant, we believe that reliance on the QAP, based on the manufacturer's knowledge of the behavior of its product, makes the most sense.

On the subject of maintenance, most commenters supported the NPRM's proposal for maintenance by manufacturers, or their representatives, and careful documentation of this activity. These provisions have been retained.

Testing Location

The NPRM called for a testing site that afforded visual and aural privacy to the employee, though in unusual circumstances a test could be conducted elsewhere. The site would have to be secured. A mobile facility (e.g., a van) that met the requirements could be used. At the site, the BAT was to supervise only one employee's use of an EBT at a time, and the BAT could not leave the site when testing was in progress. The Department, with some

modifications, is adopting this provision in the final rule. In our view, privacy in the context of breath alcohol testing is primarily for the purpose limiting other persons' access to information about the employee's test result. In contrast to urine drug testing, where private elimination functions are involved, privacy need not be as strict for breath alcohol testing. We have also eliminated references to the site being "secured," as such, because this term could lead to confusion. Our concern is that unauthorized persons not be in a position to see or overhear test results. We are not requiring that testing take place behind locked doors, in a totally enclosed space, or in a dedicated facility that is not used for other purposes.

There were few comments on this provision. Two commenters noted that privacy could be hard to achieve at a remote site. The NPRM already made allowance for this problem, however, by saying that a testing location did not have to provide full privacy in unusual circumstances such as a post-accident or reasonable suspicion test in a remote location. Other comments included a concern that privacy be protected adequately, that too much privacy could sharpen the concern about confrontations between BATs and employees, and that privacy requirements should not exclude a witness (e.g., a union representative) from the testing site. The provision establishes a general performance standard for privacy of the physical site: It does not address the issue of whether a witness may be present (that is a matter for labor-management negotiation). It does not require a site that is so isolated that a BAT could not find assistance if needed. One commenter asked for a DOT-operated national inspection program for test sites, analogous to the DHHS laboratory certification program. The Department believes that such a system would not be practicable, given the very high number of testing sites likely to be involved with the program.

Testing Form and Log Book

The NPRM proposed to require the use of a standard form for DOT-mandated testing, which employers could not modify. It would be a triplicate form, with copies for the BAT, employer, and employee. The colors of each copy of the form are intended to be consistent with the colors of the Department's drug testing form. The Department has decided to adopt this provision with minor modifications.

Seven commenters supported the NPRM provision as drafted. Thirteen commenters favored having space on

the form for recording a repeat of a test, in order to reduce paperwork. The Department believes that adding space for this purpose would result in a longer, more complicated form. Moreover, it is likely to be only in a minority of cases that a test will have to be repeated, meaning that the extra complexity of the form would not serve a useful purpose in most cases. For this reason, the Department is not adopting this comment.

Two commenters suggested that a combined drug/alcohol form be developed. The Department responds that, because of the differences between drug and alcohol testing, it would be difficult to develop a combined form that would not be too cumbersome and would work in both situations.

Two commenters asked that employers be able to modify the form. The Department's experience with the drug testing program, where some modification of the form has been permitted, is that the resulting variety of forms leads to confusion, errors, and difficulty in completing the form by collection site personnel. The Department believes that an unvarying, standard form will minimize these problems. Employers would have to use the form exactly as presented in Appendix A to this regulation (though a form directly generated by an EBT could be smaller and would not need a space to affix a separate printed result.) One commenter suggested that DOT provide the forms to employers free of charge. The Department does not believe that this is an appropriate use of Federal funds.

Two commenters asked that the form specify that the test is being conducted under the authority of DOT regulations. The Department's experience under the drug testing program is that, for lack of such a statement, some employees have been confused about whether a particular test was being conducted under DOT authority or simply under the employer's policy. The form being published with this rule includes such a statement. The result of including such a statement is that employers are not permitted to use the "DOT form" for a test not conducted under DOT authority.

Two commenters questioned the option to have the EBT or printer print results directly on the form, preferring to use a separate form. The regulation's requirements for EBTs used in confirmation testing provides this option, which is appropriate to provide flexibility. An employer who is uncomfortable with one approach can use the other.

This section of the rule includes a new provision requiring the use of a log book with EBTs, used for screening tests, that do not have the sequential numbering and printing capabilities required for devices used for confirmation tests. This section spells out the requirement for the log book and what it must contain; the rationale for the log book requirement is discussed below.

Preparation for Testing

The NPRM proposed that the BAT and the employee provide identification to one another and that the BAT explain the testing procedure to the employee. A commenter suggested that written information be provided to the employee, so that the briefing could be more detailed and the BAT had less verbal work to perform. The employer may provide the information in this fashion, though the regulation will not require it. Other comments were few and supportive. The NPRM provisions have been retained. Some provisions of this NPRM section, concerning filling out of forms and refused or incomplete tests, have been moved to the next section.

Initial Breath Test Procedures

The NPRM proposed to require an air blank before and after the screening test, which the machine had to pass in order to stay in service. The NPRM also included proposed requirements concerning completing the test paperwork.

Fifteen commenters addressed the issue of air blanks. Seven commenters agreed with the NPRM that air blanks should be required before and after each screening test. Two said that air blanks are not technically relevant with some types of EBTs. Six commenters said that an air blank should not be required after a test when the result was less than 0.02, as this was a waste of time. Some of these commenters favored pre-test air blanks, however. One commenter supported only pre-test air blanks.

The Department has decided that it will not require air blanks either before or after a screening test. First, most screening test results will be below 0.02, making post-test air blanks of limited value in those cases. Second, pre-test air blanks, at the screening stage, are not crucial in preventing "false positives" for employees, since no action against an employee may be taken without a confirmation test. Third, the Department will require air blanks before confirmation tests, which will build this protection into the testing process where it matters most. Fourth, the Department is permitting all EBTs on

the NHTSA CPL to be used in screening tests, and some of these instruments would not provide any durable record of an air blank, even if they were able to perform air blanks. Finally, the absence of a requirement for air blanks on the more frequent screening tests will result in some cumulative savings of BAT and employee time and wear on the machines.

The NPRM called for a 15-20 minute waiting period before the confirmation test; no such waiting period was proposed for before the screening test. Seven commenters favored a waiting period before the screening test, eight opposed it, and two favored employer discretion. Because the confirmation testing procedures do provide for a waiting period, and since action against an employee can be taken only on the basis of a confirmation test, we believe that requiring an additional waiting period before the screening test would be superfluous.

The NPRM provision addressed situations in which the printed and displayed results did not match, proposing that such tests would be invalid. The final rule modifies this provision, since it is irrelevant concerning instruments that do not print out a result. The NPRM provision remains in effect for EBTs that do print out.

The additional flexibility the Department has provided in screening testing procedures, by permitting the use of EBTs that do not have sequential numbering and result printing capabilities, makes it more difficult to determine that a test of a particular employee, with a particular result, has taken place, raising the possibility of cheating by employers. To mitigate this potential problem, the final rule will require a log book to be kept with each EBT used for screening that does not have the sequential numbering and printout capabilities. (This requirement does not apply to EBTs meeting the requirements for devices used for confirmation testing.) The BAT will fill out a log book entry for each test in addition to completing the alcohol testing form. The log book entries are intended to serve as a cross-check on the performance and result of a test.

There were several comments both to this section and the next section concerning whether the cutoff level for a test to which consequences for the employee would attach should be 0.02, 0.04, or, as the NPRM proposed, a bifurcated 0.02/0.04 standard, with different consequences at each level. The rule takes the latter approach, for reasons discussed in the common preamble to the OA rules.

The employee is told to sign the form after the test has been taken. If the employee does not do so, it is not regarded as a refusal to take the test. Obviously, it would be silly to regard as a refusal to take the test a refusal to sign the form after the test had already been successfully conducted. In this situation, the BAT is required to note the failure to sign in the remarks section of the form.

Confirmation Breath Test Procedures

The NPRM instructed the BAT to tell the employee to avoid eating, drinking, etc. during a 15–20 minute interval between the screening and confirmation test, though the test would continue even if the employee did not follow the directions. The BAT would also give the employee a notice not to drive or perform other safety-sensitive functions if the employee's alcohol concentration were 0.04 or greater. After performing the same steps as with the screening test, the BAT would note the alcohol concentration reading and transmit the results to the employer in a confidential manner. The lower of the two readings—screening and confirmation—would control the result.

There were 29 comments concerning the waiting period before the confirmation test, fifteen of which supported the 15-minute minimum time proposed in the NPRM. Four comments wanted a shorter interval (e.g., two or five minutes) and four supported a longer interval (e.g., 20 or 30 minutes). Two comments opposed any requirement concerning an interval. Six comments either wanted no maximum waiting time or preferred to rely on the employer's or EBT manufacturer's discretion.

The waiting period is important. It is intended to give the employee the opportunity to ensure that any residual mouth alcohol does not influence the result of the confirmation test. According to the Department's information, fifteen minutes is the minimum period after which one can be confident that any residual mouth alcohol has disappeared. A shorter interval is not feasible for this reason. At the same time, waiting a long period between tests can be costly in terms of lost employee time and could influence the outcome of the confirmation test. In order to guard against lengthy delays in the performance of confirmation tests, which can allow alcohol concentration levels to fall, the final rule retains the 20-minute maximum. It should be pointed out that failing to observe the minimum 15-minute period is a "fatal flaw" (see § 40.79 (a)), automatically invalidating a test. This is because the

Department believes it is important to prevent artificially high readings due to mouth alcohol residue. However, taking longer than 20 minutes between tests is not a "fatal flaw." The Department is aware that circumstances may sometimes result in stretching the time between tests for a few additional minutes.

Another issue addressed by commenters in a variety of ways was that of whether the screening or confirmation test result prevails when one is higher than the other. Eighteen commenters believed that the confirmation test should prevail in all cases. Two commenters supported using the higher of the two results, while three supported using the lower of the two results. The Department believes that it is more understandable, and less potentially confusing, for the confirmation test result to determine the outcome of the test. The confirmation test will always have to be performed using the most reliable methods. Also, alcohol concentration can still be rising at the time of the screening test. Although it is also possible for alcohol concentration to have dropped since the screening test, the Department's requirement for the confirmation test to be conducted a short time after the screening test should minimize any problem. Finally, this approach is consistent with that the Department takes in drug testing. Consequently, in situations in which a confirmation test is needed, the final rule will attach consequences only to the confirmation test result.

Nine commenters asked that the final rule, unlike the NPRM, provide for medical review officer (MRO) review of the confirmation test result, as the Department requires in drug testing. Among their reasons were that there could be valid medical or food-related reasons for alcohol concentrations, that there could be inadvertent alcohol consumption, that someone should review results for procedural errors, that an MRO should play the role assigned to the substance abuse professional (SAP) by the proposed rules, or that the alcohol rules should mirror the drug rules as much as possible.

In the drug testing context, an MRO determines whether there is a legitimate medical explanation for an individual having in his or her system a substance which is otherwise illegal. The alcohol rules are different in this respect. They prohibit safety sensitive employees from having alcohol concentrations above certain levels, regardless of the source of the alcohol. An alcohol concentration of 0.04 resulting from drinking beverage alcohol has the same consequences

under the rules as an alcohol concentration of 0.04 resulting from ingesting medication. Both uses of alcohol are legal (as long as they do not violate OA rules concerning on-duty use, pre-duty abstinence, etc.); the resulting alcohol concentration is prohibited by DOT regulations equally in both cases. In this context, there is nothing for an MRO to decide. Inserting an MRO into the process without this key function would add to the complexity and cost of the system without providing any benefits. For these reasons, the Department will not require MRO review of alcohol testing results.

The NPRM proposed that employers could use the same EBT for both the screening and confirmation tests. Fifteen commenters objected to this proposal. Some said that an entirely different methodology should be used for the two tests. The legal issues section of the preamble discusses this point. Others said that a different EBT should be used for each test, some making the argument that using the same machine for both tests constituted "repetition," but not "confirmation." This semantic argument is not persuasive. The statute does not require different machines to be used, as long as the machine used for the second test meets statutory requirements. (Of course, where an employer chooses to use a preliminary EBT for the screening device, it will necessarily use two different machines.) Because of the reliability of EBTs meeting the requirements of this rule, we believe it would be unnecessarily expensive to require a second device to be used, which could have the effect of roughly doubling the capital equipment costs of the program.

Twelve of thirteen commenters opposed requiring a second confirmation test after the first confirmation test had been positive, a matter about which the NPRM preamble asked a question. The Department does not see a basis for requiring a second confirmation test, and we are not adding this requirement to the final rule.

A few commenters suggested getting rid of the requirement for the BAT to notify someone testing positive that he or she should not drive. The Department has decided to include a notice to this effect on the alcohol testing form, making direct participation by the BAT unnecessary.

Two commenters suggested that the rule be clarified to indicate that an employer could have more than one representative to whom results are transmitted. The Department has done so.

Two comments supported, and two opposed, the practice of back extrapolation to obtain a result. The Department's NPRMs proposed that the consequences of test results attach only to employees whose EBT readings were in fact at the stated levels. The Department did not propose to attach these consequences to inferences from EBT readings about what an employee's alcohol concentration might have been at an earlier point. For example, if an employee's EBT test result were .03, the requirement that the individual not again perform safety-sensitive functions until he or she was evaluated by a substance abuse professional (SAP) and had passed a return-to-duty test, and the requirement that the individual be subject to follow-up testing, would not apply because the employer, SAP, or other party believed that the individual's alcohol concentration had been 0.04 or greater prior to the test. Given the wide individual variations in alcohol metabolism among individuals, such inferences involve considerable uncertainty. The Department is retaining the NPRM provision on this point. This would not prevent an OA from making use of back extrapolation in certain situations (e.g., FRA makes some use of back extrapolation in its existing toxicological testing program, in a context involving the use of samples of two different body fluids; inquiries into accident causation or proceedings to revoke DOT-issued certificates or licenses held by employees, where expert testimony can be produced with the protection of the due process procedures of a hearing). These situations are different from the use of back extrapolation by employers in interpreting the results of tests conducted under part 40, however.

There will be some cases in which the BAT who conducts the screening test and the BAT who conducts the confirmation test are different people. For example, BAT #1 conducts a screening test, using an EBT not having sequential numbering or printout capabilities, in location A. The confirmation test, using a device that has these features, happens subsequently in location B, and is conducted by BAT #2. In such a case, to minimize the possibility of lost forms or other errors, the final rule provides that BAT #1 would complete the form for the screening test and give the employee his or her copy of the form. BAT #2 would then start a new form. The sections of the rule concerning screening and confirmation testing procedures have been modified to this effect.

Refused and Incomplete Tests

The final rule, in § 40.67, picks up paragraphs from the NPRM that do not fit conveniently in other sections. The first provides that employee refusals to take certain actions (e.g., complete and sign Step 2 of the form, provide breath) constitute a refusal to be tested. Such refusals, under the operating administration rules, have the same consequences as a test result of 0.04 or greater. The NPRM provision on which this paragraph is based was not the subject of comment. The second paragraph provides that if a test cannot be completed, or an event occurs that would invalidate the test, the BAT would, if practicable, run a retest. All seventeen comments on the subject favored this approach, and the Department is including it in the final rule.

Inability to Provide Sufficient Breath

The NPRM proposed that if an employee were unable to provide enough breath for an adequate sample, the BAT would ask the employee to try again. If the same result occurred, then the employee would be referred to a doctor for a medical evaluation. If the doctor determined that the inability to provide breath was due, or probably due, to a medical condition, the failure to provide the sample would be excused. If not, it would be treated as a refusal.

Four comments supported the NPRM provision. Three others thought that this situation was unlikely to arise, since only an employee who was seriously disabled, unconscious, or dead would be unable to provide the modest quantity of breath required to complete a test. We agree that this situation should not occur frequently, but we believe it is sensible to have a procedure in place to handle the occasional occurrence.

Nine commenters suggested that, if the employee cannot provide sufficient breath, the employee should be required to provide a sample of a body fluid (e.g., blood, urine). Two comments urged employer discretion in these cases. Ten commenters said that there should be a medical evaluation in all cases where an employee cannot produce sufficient breath, though these commenters disagreed with each other about whether the employee should be held out of safety-sensitive functions pending the result of the evaluation.

Under the final rule, the employer is required to direct the employee to be medically evaluated in "shy lung" cases. The final rule directs the employer to ensure that this evaluation

occurs as soon as possible. Employers, under their own authority, could choose to "stand down" an employee pending the result of a medical evaluation, but the rule does not require this step.

In addition, the accompanying NPRM proposes that blood testing may be used in post-accident and reasonable suspicion testing when an EBT is not readily available. Since blood testing, and procedures for it, may become part of the rule for these purposes, the Department is responding to these comments by proposing blood testing as an option (regardless of the type of testing involved) when an employee cannot provide a sufficient breath sample. If the NPRM's proposal is made part of a final rule, the employer would have discretion concerning which alternative (blood alcohol testing or a medical evaluation) to select. Persons interested in this issue are asked to comment to the NPRM docket.

Invalid Tests

The original NPRM listed nine "fatal flaws" that would invalidate breath tests. An invalid test is neither positive nor negative, and it has no consequences for an employee. The NPRM being published today proposes a similar list of fatal flaws for blood tests.

The NPRM proposed that failure to observe the 15-minute minimum waiting period before the confirmation test would be a fatal flaw; going over the 20-minute maximum would not. Comments generally agreed with this approach, some noting that if exceeding a maximum waiting time were to be a fatal flaw, the outer limit should be 30 or 60 minutes rather than 20. One commenter opposed making observance of the minimum a fatal flaw. The Department is retaining the NPRM provision on this point.

The Department is changing the provision concerning air blanks to reflect the final rule's requirement of an air blank before only the confirmation test. Likewise, the NPRM provision making the device's failure to print out a result a fatal flaw has been changed to apply only to confirmation tests. The provision on disagreement between the printout and the machine display concerning sequential test numbers or alcohol concentration has been modified for the same reason. If the employee fails to sign Step 4 of the form, that is not a fatal flaw; the BAT's failure to note the employee's failure to sign that portion of the form would be a fatal flaw, however.

The NPRM proposed that if an EBT fails an external calibration check, every test performed on the device since the

last valid external calibration test would be invalidated. Ten commenters opposed this provision, pointing out that it would cause numerous problems for employers if they had to invalidate tests after the fact, and perhaps had to reverse personnel actions as well. Four commenters supported the proposed requirement. The Department is well aware that after-the-fact invalidations of tests can create serious problems for employers. The Department does not see a workable alternative, however. If a valid external calibration check was performed after test A, and an invalid external calibration test was performed after test K, all we know for certain is that the machine went out of kilter somewhere between tests B and K. We cannot say for certain that test B or C was valid, or assume that the error occurred only on test K. Since we cannot determine that these tests were valid, we must, in fairness to the employees involved, treat them as invalid. Tests with results of 0.02 and above would be deemed invalid in this situation. This is surely incentive for employers to conduct frequent external calibration checks, particularly after positive tests.

One commenter suggested additional fatal flaws, such as failure to use a clean mouthpiece, inadequate grounds for reasonable suspicion, etc. One commenter suggested that all flaws should be regarded as fatal. The Department believes that only certain serious problems in the process, that directly affect the integrity of the test or accuracy of the result, should automatically invalidate the test. Other errors, particularly in combination with one another, could form the basis for a determination that a test is invalid (i.e., the listed fatal flaws are not intended to be the only possible grounds for invalidation). The Office of Drug Enforcement and Program Compliance is charged with providing, on behalf of the Department, definitive guidance on issues concerning the invalidation of tests.

Availability of Testing Information

The NPRM proposed provisions on alcohol test information availability parallel to the existing provisions on the availability of drug testing information, as the Department has interpreted them. Employers could release information to a third party only with the specific written consent of the employee, must keep confidential information secure, but may make the information available in certain litigation situations. Employers must make information available to DOT or, under some circumstances, to the National

Transportation Safety Board (NTSB). Employers must also make information about an employee's test available to that employee.

Seven commenters, most of whom were from the motor carrier industry, asked that employers be authorized or required to make testing information available to third parties without the employee's consent. In this industry, the commenters said, there was a high turnover rate. Employees move rapidly from employer to employer. In the absence of authorization or requirement for a former employer to provide testing information to a potential new employer, either the hiring process would be slowed or important information about positive tests in the employee's past would be unavailable to the new employer.

In response, the Department points out that an employer may, without authorization from DOT, require an applicant, as a condition of employment, to give written consent to the disclosure of this information by a former employer. The Department is adding a sentence to this provision of the rule telling employers that they must provide the information when the employee consents to its transmission to a third party. However, in order to maintain the confidentiality of sensitive information, in which employees have a significant privacy interest, the Department will not authorize the transmission of this information among employers or potential employers without written employee consent.

The Department emphasizes that the consent involved must be a specific written consent for information to be sent from one named party to another named party. Blanket consents (i.e., a consent for testing information to be sent to all present or future employers or members of a consortium) are not permitted. Each consent must pertain to one specific employer providing the information about a particular employee to another specific employer.

Two commenters suggested that an employee should not have to pay for obtaining information in his or her own file concerning alcohol tests. The Department believes that this is a matter better left to employer-employee agreements. As the Department interprets this provision, employers may impose reasonable charges to cover the cost of retrieval, copying, and transmission of the records requested. The employer is also expected only to provide copies within its possession or control (including documents that may be maintained by a consortium or third-party provider that conducted testing for the employer).

Records Concerning BATs and EBTs

The NPRM proposed that the employer maintain various records concerning EBTs and BATs for five years. One commenter suggested that consortia and third-party providers be authorized to keep the records instead of the employer. The Department agrees that this is reasonable, and the final rule requires the employer or its agent to maintain the records. The employer retains ultimate responsibility for producing the records, however. Two commenters suggested we reduce the record retention period to two years, while one commenter said that the recordkeeping requirements in the NPRM were not burdensome. Consistent with the OA rules, the final part 40 rule establishes a 5-year retention period for calibration records and a two-year retention period for other records.

Other Issues

A number of commenters asked that we modify the definition of alcohol to include alcohols other than ethanol (e.g., methanol, isopropanol), in order to avoid loopholes in the program that would allow an employee to claim that his or her alcohol concentration reading was the result of ingesting a non-ethanol substance. The Department agrees that the definition should be broadened to avoid any potential problems with the use of non-ethanol alcohols, and the final rule includes a modified definition to this effect. This revised definition is consistent with that used by NHTSA in its model specifications for evidential EBTs. We have also added a companion definition of alcohol use, which emphasizes that any consumption of a preparation including alcohol (e.g., beverages, medicines) counts as alcohol use.

A few commenters asked that, for convenience, we centralize all the definitions in part 40 in one section. We have done so, and all the definitions are now in § 40.3.

The NPRM preamble asked for suggestions on how to deal with situations in which an arbitrator overturns an employer's personnel action based on an alcohol test result. Employers had expressed concern about perceived conflicts between the arbitrator's decisions and DOT regulations, and several commenters echoed these concerns. The Department is not convinced, however, that this problem is either frequent enough or serious enough to warrant a mandate in the regulatory text. Such a mandate, because it could not anticipate all the nuances of the factual situations involved, might interfere with

reasonable resolutions of particular disputes.

However, it is clear that employers are obligated to comply with DOT safety regulations, which have the force and effect of law. As a matter of law, no decision by an employer, employee organization, or individual or group appointed by those or other parties, can have the effect of excusing noncompliance by an employer with a provision of a DOT safety regulation. If a violation of DOT rules has occurred, then the consequences prescribed by DOT rules must follow (e.g., the employee must be removed from performing a safety-sensitive function).

In the NPRM preamble, the Department included a discussion of handling of perceived conflicts between part 40 and operating administration regulations, exemptions, and the obligations of consortia and third-party providers (57 FR 59410; December 15, 1992). This discussion applies to the implementation of the final part 40 as well. The relevant language is reprinted below:

Although implementation of part 40 generally would be done through an operating administration, part 40 is an Office of the Secretary of Transportation (OST) regulation. As such, requests for exemption would be processed under 49 CFR part 5, an existing regulation covering requests for exemption from or amendment to all OST rules, rather than through separate operating administration exemption procedures. This would add an additional element of consistency. This approach is consistent with the existing part 40 drug testing procedures, from which exemptions would also be granted under part 40. (See 54 FR 49863; December 1, 1989).

The grant of an exemption under part 40 must be based on special or exceptional circumstances. It is not appropriate to carve out a generally applicable exception to a rule. Also, an exemption must be based on circumstances not contemplated as part of the rulemaking. The exemption process is not designed to revisit issues settled in the rulemaking process.

Section 40.1 would also emphasize that other parties involved in the testing process—such as consortia, contractors, and agents—"stand in the shoes" of the employer. They are, therefore, subject to the same obligations and requirements as the employer. If an employer is required to do something, so is the consortium that is conducting testing for the employer. If the consortium fails to do something correctly, the employer is in noncompliance.

Since, as noted above, part 40 is a regulation of the Office of the Secretary of Transportation, the source of definitive interpretations of the rule is the Office of the Secretary. Interpretations have been and will continue to be made in close

coordination among the OAs, the Office of Drug Enforcement and Program Compliance (DEPC), and the Office of General Counsel.

Regulatory Analyses and Notices

Because of substantial public interest and substantial impacts on a wide range of private and public sector organizations, the Department has determined that this rule—in conjunction with the operating administration alcohol and drug testing rules—is significant under Executive Order 12866. The rule has been reviewed under this Order. It is also significant under the Department's regulatory policies and procedures. The Department has prepared a regulatory evaluation for part 40, which we have included in the docket. The costs of the application of part 40 procedures to the programs of the various OAs are estimated in each of the OAs' regulatory evaluations for their drug and alcohol rules being published today.

This rule, in conjunction with the operating administration drug and alcohol testing rules, is likely to have a significant economic impact on a substantial number of small entities. These impacts are assessed in the OAs' regulatory evaluations. The Federalism impacts of this rule are either minimal or required by statute; for these reasons, we have not prepared a Federalism assessment.

This rule also contains collection of information requirements. The Department has submitted these requirements to the Office of Management and Budget for review and approval under the Paperwork Reduction Act (44 U.S.C. 350, *et. seq.*). Please see the Common Preamble on the status of Paperwork Reduction Act approvals.

List of Subjects in 49 CFR Part 40

Drug testing, Reporting and recordkeeping requirements, Safety, Transportation.

Issued This 25th day of January, 1994, at Washington, D.C.

Federico Peña,

Secretary of Transportation.

David R. Hinson,

Administrator, Federal Aviation Administration.

Rodney E. Slater,

Administrator, Federal Highway Administration.

Jolene M. Molitoris,

Administrator, Federal Railroad Administration.

Gordon J. Linton,

Administrator, Federal Transit Administration.

Ana Sol Gutiérrez,

Acting Administrator, Research and Special Programs Administration.

Adm. J. William Kime,

Commandant, United States Coast Guard.

For the reasons set forth in the preamble, the Department of Transportation amends Title 49, Code of Federal Regulations, part 40, as follows:

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

1. The authority citation for Part 40 is revised to read as follows:

Authority: 49 U.S.C. 102, 301, 322; 49 U.S.C. app. 1301nt., app. 1434nt., app. 2717, app. 1618a.

2. §§ 40.1 through 40.19 are designated as subpart A and revised to read as follows:

Subpart A—General

40.1 Applicability.

40.3 Definitions.

40.5–40.19 [Reserved]

Subpart A—GENERAL

§ 40.1 Applicability.

This part applies, through regulations that reference it issued by agencies of the Department of Transportation, to transportation employers, including self-employed individuals, required to conduct drug and/or alcohol testing programs by DOT agency regulations and to such transportation employers' officers, employees, agents and contractors (including, but not limited to, consortia). Employers are responsible for the compliance of their officers, employees, agents, consortia and/or contractors with the requirements of this part.

§ 40.3 Definitions.

The following definitions apply to this part:

Air blank. A reading by an EBT of ambient air containing no alcohol. (In

EBTs using gas chromatography technology, a reading of the device's internal standard.)

Alcohol. The intoxicating agent in beverage alcohol, ethyl alcohol or other low molecular weight alcohols including methyl or isopropyl alcohol.

Alcohol concentration. The alcohol in a volume of breath expressed in terms of grams of alcohol per 210 liters of breath as indicated by a breath test under this part.

Alcohol use. The consumption of any beverage, mixture or preparation, including any medication, containing alcohol.

Aliquot. A portion of a specimen used for testing.

Blind sample or blind performance test specimen. A urine specimen submitted to a laboratory for quality control testing purposes, with a fictitious identifier, so that the laboratory cannot distinguish it from employee specimens, and which is spiked with known quantities of specific drugs or which is blank, containing no drugs.

Breath Alcohol Technician (BAT). An individual who instructs and assists individuals in the alcohol testing process and operates an EBT.

Canceled or invalid test. In drug testing, a drug test that has been declared invalid by a Medical Review Officer. A canceled test is neither a positive nor a negative test. For purposes of this part, a sample that has been rejected for testing by a laboratory is treated the same as a canceled test. In alcohol testing, a test that is deemed to be invalid under § 40.79. It is neither a positive nor a negative test.

Chain of custody. Procedures to account for the integrity of each urine or blood specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. With respect to drug testing, these procedures shall require that an appropriate drug testing custody form (see § 40.23(a)) be used from time of collection to receipt by the laboratory and that upon receipt by the laboratory an appropriate laboratory chain of custody form(s) account(s) for the sample or sample aliquots within the laboratory.

Collection container. A container into which the employee urinates to provide the urine sample used for a drug test.

Collection site. A place designated by the employer where individuals present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

Collection site person. A person who instructs and assists individuals at a collection site and who receives and

makes a screening examination of the urine specimen provided by those individuals.

Confirmation (or confirmatory) test. In drug testing, a second analytical procedure to identify the presence of a specific drug or metabolite that is independent of the screening test and that uses a different technique and chemical principle from that of the screening test in order to ensure reliability and accuracy. (Gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.) In alcohol testing, a second test, following a screening test with a result of 0.02 or greater, that provides quantitative data of alcohol concentration.

DHHS. The Department of Health and Human Services or any designee of the Secretary, Department of Health and Human Services.

DOT agency. An agency of the United States Department of Transportation administering regulations related to drug or alcohol testing, including the United States Coast Guard (for drug testing purposes only), the Federal Aviation Administration, the Federal Railroad Administration, the Federal Highway Administration, the Federal Transit Administration, the Research and Special Programs Administration, and the Office of the Secretary.

Employee. An individual designated in a DOT agency regulation as subject to drug testing and/or alcohol testing. As used in this part "employee" includes an applicant for employment. "Employee" and "individual" or "individual to be tested" have the same meaning for purposes of this part.

Employer. An entity employing one or more employees that is subject to DOT agency regulations requiring compliance with this part. As used in this part, employer includes an industry consortium or joint enterprise comprised of two or more employing entities.

EBT (or evidential breath testing device). An EBT approved by the National Highway Traffic Safety Administration (NHTSA) for the evidential testing of breath and placed on NHTSA's "Conforming Products List of Evidential Breath Measurement Devices" (CPL).

Medical Review Officer (MRO). A licensed physician (medical doctor or doctor of osteopathy) responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an

individual's confirmed positive test result together with his or her medical history and any other relevant biomedical information.

Screening test (or initial test). In drug testing, an immunoassay screen to eliminate "negative" urine specimens from further analysis. In alcohol testing, an analytic procedure to determine whether an employee may have a prohibited concentration of alcohol in a breath specimen.

Secretary. The Secretary of Transportation or the Secretary's designee.

Shipping container. A container capable of being secured with a tamper-evident seal that is used for transfer of one or more urine specimen bottle(s) and associated documentation from the collection site to the laboratory.

Specimen bottle. The bottle that, after being labeled and sealed according to the procedures in this part, is used to transmit a urine sample to the laboratory.

§§ 40.5—40.19 [Reserved]

2. §§ 40.21 through 40.39 are designated subpart B.

Subpart B—Drug Testing

- 40.21 The drugs.
- 40.23 Preparation for testing.
- 40.25 Specimen collection procedures.
- 40.27 Laboratory personnel.
- 40.29 Laboratory analysis procedures.
- 40.31 Quality assurance and quality control.
- 40.33 Reporting and review of results.
- 40.35 Protection of employee records.
- 40.37 Individual access to test and laboratory certification results.
- 40.39 Use of DHHS—certified laboratories.

Authority: 49 U.S.C. 102, 301, 322; 49 U.S.C. app. 1301nt., app. 1434nt., app. 2717, app. 1618a.

3. In § 40.25, paragraph (f)(10) is revised to read as follows:

§ 40.25 Specimen collection procedures.

* * * * *

(f) * * *

(10) The collection site person shall instruct the employee to provide at least 45 ml of urine under the split sample method of collection or 30 ml of urine under the single sample method of collection.

(i)(A) Employers with employees subject to drug testing only under the drug testing rules of the Research and Special Programs Administration and/or Coast Guard may use the "split sample" method of collection or may collect a single sample for those employees.

(B) Employers with employees subject to drug testing under the drug testing rules of the Federal Highway Administration, Federal Railroad

Administration, Federal Transit Administration, or Federal Aviation Administration shall use the "split sample" method of collection for those employees.

(ii) Employers using the split sample method of collection shall follow the procedures in this paragraph (f)(10)(ii):

(A) The donor shall urinate into a collection container or a specimen bottle capable of holding at least 60 ml.

(B) If a collection container is used, the collection site person, in the presence of the donor, pours the urine into two specimen bottles. Thirty (30) ml shall be poured into one bottle, to be used as the primary specimen. At least 15 ml shall be poured into the other bottle, to be used as the split specimen.

(C) If a single specimen bottle is used as a collection container, the collection site person shall pour 30 ml of urine from the specimen bottle into a second specimen bottle (to be used as the primary specimen) and retain the remainder (at least 15 ml) in the collection bottle (to be used as the split specimen).

(D) Both bottles shall be shipped in a single shipping container, together with copies 1, 2, and the split specimen copy of the chain of custody form, to the laboratory.

(E) If the test result of the primary specimen is positive, the employee may request that the MRO direct that the split specimen be tested in a different DHHS-certified laboratory for presence of the drug(s) for which a positive result was obtained in the test of the primary specimen. The MRO shall honor such a request if it is made within 72 hours of the employee having been notified of a verified positive test result.

(F) When the MRO informs the laboratory in writing that the employee has requested a test of the split specimen, the laboratory shall forward, to a different DHHS-approved laboratory, the split specimen bottle, with seal intact, a copy of the MRO request, and the split specimen copy of the chain of custody form with appropriate chain of custody entries.

(G) The result of the test of the split specimen is transmitted by the second laboratory to the MRO.

(H) Action required by DOT agency regulations as the result of a positive drug test (e.g., removal from performing a safety-sensitive function) is not stayed pending the result of the test of the split specimen.

(I) If the result of the test of the split specimen fails to reconfirm the presence of the drug(s) or drug metabolite(s) found in the primary specimen, the MRO shall cancel the test, and report the cancellation and the reasons for it to

the DOT, the employer, and the employee.

(iii) Employers using the single sample collection method shall follow the procedures in paragraph:

(A) The collector may choose to direct the employee to urinate either directly into a specimen bottle or into a separate collection container.

(B) If a separate collection container is used, the collection site person shall pour at least 30 ml of the urine from the collection container into the specimen bottle in the presence of the employee.

(iv) In either collection methodology, upon receiving the specimen from the individual, the collection site person shall determine if it has at least 30 milliliters of urine for the primary or single specimen bottle and, where the split specimen collection method is used, an additional 15 ml of urine for the split specimen bottle. If the individual is unable to provide such a quantity of urine, the collection site person shall instruct the individual to drink not more than 24 ounces of fluids and, after a period of up to two hours, again attempt to provide a complete sample using a fresh collection container. The original insufficient specimen shall be discarded. If the employee is still unable to provide an adequate specimen, the insufficient specimen shall be discarded, testing discontinued, and the employer so notified. The MRO shall refer the individual for a medical evaluation to develop pertinent information concerning whether the individual's inability to provide a specimen is genuine or constitutes a refusal to test. (In preemployment testing, if the employer does not wish to hire the individual, the MRO is not required to make such a referral.) Upon completion of the examination, the MRO shall report his or her conclusions to the employer in writing.

* * * * *

4. In § 40.29, paragraph (b)(2) is revised and paragraph (b)(3) is added, as follows:

§ 40.29 Laboratory analysis procedures.

* * * * *

(b) * * * * *

(2) In situations where the employer uses the split sample collection method, the laboratory shall log in the split specimen, with the split specimen bottle seal remaining intact. The laboratory shall store this sample securely (see paragraph (c) of this section). If the result of the test of the primary specimen is negative, the laboratory may discard the split specimen. If the result of the test of the primary specimen is positive, the laboratory

shall retain the split specimen in frozen storage for 60 days from the date on which the laboratory acquires it (see paragraph (h) of this section). Following the end of the 60-day period, if not informed by the MRO that the employee has requested a test of the split specimen, the laboratory may discard the split specimen.

(3) When directed in writing by the MRO to forward the split specimen to another DHHS-certified laboratory for analysis, the second laboratory shall analyze the split specimen by GC/MS to reconfirm the presence of the drug(s) or drug metabolite(s) found in the primary specimen. Such GC/MS confirmation shall be conducted without regard to the cutoff levels of § 40.29(f). The split specimen shall be retained in long-term storage for one year by the laboratory conducting the analysis of the split specimen (or longer if litigation concerning the test is pending).

* * * * *

6. In § 40.33 paragraphs (e), (f) and (g) are revised; paragraph (h) is redesignated as paragraphs (i), and a new paragraph (h) is added, as follows:

§ 40.33 Reporting and review of results.

* * * * *

(e) In a situation in which the employer has used the single sample method of collection, the MRO shall notify each employee who has a confirmed positive test that the employee has 72 hours in which to request a reanalysis of the original specimen, if the test is verified positive. If requested to do so by the employee within 72 hours of the employee's having been informed of a verified positive test, the Medical Review Officer shall direct, in writing, a reanalysis of the original sample. The MRO may also direct, in writing, such a reanalysis if the MRO questions the accuracy or validity of any test result. Only the MRO may authorize such a reanalysis, and such a reanalysis may take place only at laboratories certified by DHHS. If the reanalysis fails to reconfirm the presence of the drug or drug metabolite, the MRO shall cancel the test and report the cancellation and the reasons for it to the DOT, the employer and the employee.

(f) In situations in which the employer uses the split sample method of collection, the MRO shall notify each employee who has a confirmed positive test that the employee has 72 hours in which to request a test of the split specimen, if the test is verified as positive. If the employee requests an analysis of the split specimen within 72 hours of having been informed of a verified positive test, the MRO shall

direct, in writing, the laboratory to provide the split specimen to another DHHS-certified laboratory for analysis. If the analysis of the split specimen fails to reconfirm the presence of the drug(s) or drug metabolite(s) found in the primary specimen, or if the split specimen is unavailable, inadequate for testing or untestable, the MRO shall cancel the test and report cancellation and the reasons for it to the DOT, the employer, and the employee.

(g) If an employee has not contacted the MRO within 72 hours, as provided in paragraphs (e) and (f) of this section, the employee may present to the MRO information documenting that serious illness, injury, inability to contact the MRO, lack of actual notice of the verified positive test, or other circumstances unavoidably prevented the employee from timely contacting the MRO. If the MRO concludes that there is a legitimate explanation for the employee's failure to contact the MRO within 72 hours, the MRO shall direct that the reanalysis of the primary specimen or analysis of the split specimen, as applicable, be performed.

(h) When the employer uses the split sample method of collection, the employee is not authorized to request a reanalysis of the primary specimen as provided in paragraph (e) of this section.

* * *

7. A new subpart C is added to part 40, to read as follows:

Subpart C—Alcohol Testing

- 40.51 The breath alcohol technician.
- 40.53 Devices to be used for breath alcohol tests.
- 40.55 Quality assurance plans for EBTs.
- 40.57 Locations for breath alcohol testing.
- 40.59 The breath alcohol testing form and log book.
- 40.61 Preparation for breath alcohol testing.
- 40.63 Procedures for screening tests.
- 40.65 Procedures for confirmation tests.
- 40.67 Refusals to test and uncompleted tests.
- 40.69 Inability to provide an adequate amount of breath.
- 40.71 [Reserved]
- 40.73 [Reserved]
- 40.75 [Reserved]
- 40.77 [Reserved]
- 40.79 Invalid Tests.
- 40.81 Availability and disclosure of alcohol testing information about individual employees.
- 40.83 Maintenance and disclosure of records concerning EBTs and BATs.

Appendix A—The Breath Alcohol Testing Form

Authority: 49 U.S.C. 102, 301, 322; 49 U.S.C. app. 1301nt., app. 1434nt., app. 2717, app. 1618a.

§ 40.51 The breath alcohol technician.

(a) The breath alcohol technician (BAT) shall be trained to proficiency in the operation of the EBT he or she is using and in the alcohol testing procedures of this part.

(1) Proficiency shall be demonstrated by successful completion of a course of instruction which, at a minimum, provides training in the principles of EBT methodology, operation, and calibration checks; the fundamentals of breath analysis for alcohol content; and the procedures required in this part for obtaining a breath sample, and interpreting and recording EBT results.

(2) Only courses of instruction for operation of EBTs that are equivalent to the Department of Transportation model course, as determined by the National Highway Traffic Safety Administration (NHTSA), may be used to train BATs to proficiency. On request, NHTSA will review a BAT instruction course for equivalency.

(3) The course of instruction shall provide documentation that the BAT has demonstrated competence in the operation of the specific EBT(s) he/she will use.

(4) Any BAT who will perform an external calibration check of an EBT shall be trained to proficiency in conducting the check on the particular model of EBT, to include practical experience and demonstrated competence in preparing the breath alcohol simulator or alcohol standard, and in maintenance and calibration of the EBT.

(5) The BAT shall receive additional training, as needed, to ensure proficiency, concerning new or additional devices or changes in technology that he or she will use.

(6) The employer or its agent shall establish documentation of the training and proficiency test of each BAT it uses to test employees, and maintain the documentation as provided in § 40.83.

(b) A BAT-qualified supervisor of an employee may conduct the alcohol test for that employee only if another BAT is unavailable to perform the test in a timely manner. A supervisor shall not serve as a BAT for the employee in any circumstance prohibited by a DOT operating administration regulation.

(c) Law enforcement officers who have been certified by state or local governments to conduct breath alcohol testing are deemed to be qualified as BATs. In order for a test conducted by such an officer to be accepted under Department of Transportation alcohol testing requirements, the officer must have been certified by a state or local government to use the EBT that was used for the test.

§ 40.53 Devices to be used for breath alcohol tests.

(a) For screening tests, employers shall use only EBTs. When the employer uses for a screening test an EBT that does not meet the requirements of paragraphs (b) (1) through (3) of this section, the employer shall use a log book in conjunction with the EBT (see § 40.59(c)).

(b) For confirmation tests, employers shall use EBTs that meet the following requirements:

(1) EBTs shall have the capability of providing, independently or by direct link to a separate printer, a printed result in triplicate (or three consecutive identical copies) of each breath test and of the operations specified in paragraphs (b) (2) and (3) of this section.

(2) EBTs shall be capable of assigning a unique and sequential number to each completed test, with the number capable of being read by the BAT and the employee before each test and being printed out on each copy of the result.

(3) EBTs shall be capable of printing out, on each copy of the result, the manufacturer's name for the device, the device's serial number, and the time of the test.

(4) EBTs shall be able to distinguish alcohol from acetone at the 0.02 alcohol concentration level.

(5) EBTs shall be capable of the following operations:

- (i) Testing an air blank prior to each collection of breath; and
- (ii) Performing an external calibration check.

§ 40.55 Quality assurance plans for EBTs.

(a) In order to be used in either screening or confirmation alcohol testing subject to this part, an EBT shall have a quality assurance plan (QAP) developed by the manufacturer.

(1) The plan shall designate the method or methods to be used to perform external calibration checks of the device, using only calibration devices on the NHTSA "Conforming Products List of Calibrating Units for Breath Alcohol Tests."

(2) The plan shall specify the minimum intervals for performing external calibration checks of the device. Intervals shall be specified for different frequencies of use, environmental conditions (e.g., temperature, altitude, humidity), and contexts of operation (e.g., stationary or mobile use).

(3) The plan shall specify the tolerances on an external calibration check within which the EBT is regarded to be in proper calibration.

(4) The plan shall specify inspection, maintenance, and calibration

requirements and intervals for the device.

(5) For a plan to be regarded as valid, the manufacturer shall have submitted the plan to NHTSA for review and have received NHTSA approval of the plan.

(b) The employer shall comply with the NHTSA-approved quality assurance plan for each EBT it uses for alcohol screening or confirmation testing subject to this part.

(1) The employer shall ensure that external calibration checks of each EBT are performed as provided in the QAP.

(2) The employer shall take an EBT out of service if any external calibration check results in a reading outside the tolerances for the EBT set forth in the QAP. The EBT shall not again be used for alcohol testing under this part until it has been serviced and has had an external calibration check resulting in a reading within the tolerances for the EBT.

(3) The employer shall ensure that inspection, maintenance, and calibration of each EBT are performed by the manufacturer or a maintenance representative certified by the device's manufacturer or a state health agency or other appropriate state agency. The employer shall also ensure that each BAT or other individual who performs an external calibration check of an EBT used for alcohol testing subject to this part has demonstrated proficiency in conducting such a check of the model of EBT in question.

(4) The employer shall maintain records of the external calibration checks of EBTs as provided in § 40.83.

(c) When the employer is not using the EBT at an alcohol testing site, the employer shall store the EBT in a secure space.

§ 40.57 Locations for breath alcohol testing.

(a) Each employer shall conduct alcohol testing in a location that affords visual and aural privacy to the individual being tested, sufficient to prevent unauthorized persons from seeing or hearing test results. All necessary equipment, personnel, and materials for breath testing shall be provided at the location where testing is conducted.

(b) An employer may use a mobile collection facility (e.g., a van equipped for alcohol testing) that meets the requirements of paragraph (a) of this section.

(c) No unauthorized persons shall be permitted access to the testing location when the EBT remains unsecured or, in order to prevent such persons from seeing or hearing a testing result, at any time when testing is being conducted.

(d) In unusual circumstances (e.g., when it is essential to conduct a test outdoors at the scene of an accident), a test may be conducted at a location that does not fully meet the requirements of paragraph (a) of this section. In such a case, the employer or BAT shall provide visual and aural privacy to the employee to the greatest extent practicable.

(e) The BAT shall supervise only one employee's use of the EBT at a time. The BAT shall not leave the alcohol testing location while the testing procedure for a given employee (see §§ 40.61 through 40.65) is in progress.

§ 40.59 The breath alcohol testing form and log book.

(a) Each employer shall use the breath alcohol testing form prescribed under this part. The form is found in appendix A to this subpart. Employers may not modify or revise this form, except that a form directly generated by an EBT may omit the space for affixing a separate printed result to the form.

(b) The form shall provide triplicate (or three consecutive identical) copies. Copy 1 (white) shall be retained by the BAT. Copy 2 (green) shall be provided to the employee. Copy 3 (blue) shall be transmitted to the employer. Except for a form generated by an EBT, the form shall be 8½ by 11 inches in size.

(c) A log book shall be used in conjunction with any EBT used for screening tests that does not meet the requirements of § 40.53(b) (1) through (3). There shall be a log book for each such device, that is not used in conjunction with any other device and that is used to record every test conducted on the device. The log book shall include columns for the test number, date of the test, name of the BAT, location of the test, quantified test result, and initials of the employee taking each test.

§ 40.61 Preparation for breath alcohol testing.

(a) When the employee enters the alcohol testing location, the BAT will require him or her to provide positive identification (e.g., through use of a photo I.D. card or identification by an employer representative). On request by the employee, the BAT shall provide positive identification to the employee.

(b) The BAT shall explain the testing procedure to the employee.

§ 40.63 Procedures for screening tests.

(a) The BAT shall complete Step 1 on the Breath Alcohol Testing Form. The employee shall then complete Step 2 on the form, signing the certification. Refusal by the employee to sign this

certification shall be regarded as a refusal to take the test.

(b) An individually-sealed mouthpiece shall be opened in view of the employee and BAT and attached to the EBT in accordance with the manufacturer's instructions.

(c) The BAT shall instruct the employee to blow forcefully into the mouthpiece for at least 6 seconds or until the EBT indicates that an adequate amount of breath has been obtained.

(d)(1) If the EBT does not meet the requirements of § 40.53(b)(1) through (3), the BAT and the employee shall take the following steps:

(i) Show the employee the result displayed on the EBT. The BAT shall record the displayed result, test number, testing device, serial number of the testing device, time and quantified result in Step 3 of the form.

(ii) Record the test number, date of the test, name of the BAT, location, and quantified test result in the log book. The employee shall initial the log book entry.

(2) If the EBT provides a printed result, but does not print the results directly onto the form, the BAT shall show the employee the result displayed on the EBT. The BAT shall then affix the test result printout to the breath alcohol test form in the designated space, using a method that will provide clear evidence of removal (e.g., tamper-evident tape).

(3) If the EBT prints the test results directly onto the form, the BAT shall show the employee the result displayed on the EBT.

(e)(1) In any case in which the result of the screening test is a breath alcohol concentration of less than 0.02, the BAT shall date the form and sign the certification in Step 3 of the form. The employee shall sign the certification and fill in the date in Step 4 of the form.

(2) If the employee does not sign the certification in Step 4 of the form or does not initial the log book entry for a test, it shall not be considered a refusal to be tested. In this event, the BAT shall note the employee's failure to sign or initial in the "Remarks" section of the form.

(3) If a test result printed by the EBT (see paragraph (d)(2) or (d)(3) of this section) does not match the displayed result, the BAT shall note the disparity in the remarks section. Both the employee and the BAT shall initial or sign the notation. In accordance with § 40.79, the test is invalid and the employer and employee shall be so advised.

(4) No further testing is authorized. The BAT shall transmit the result of less than 0.02 to the employer in a

confidential manner, and the employer shall receive and store the information so as to ensure that confidentiality is maintained as required by § 40.81.

(f) If the result of the screening test is an alcohol concentration of 0.02 or greater, a confirmation test shall be performed as provided in § 40.65.

(g) If the confirmation test will be conducted by a different BAT, the BAT who conducts the screening test shall complete and sign the form and log book entry. The BAT will provide the employee with Copy 2 of the form.

§ 40.65 Procedures for confirmation tests.

(a) If a BAT other than the one who conducted the screening test is conducting the confirmation test, the new BAT shall follow the procedures of § 40.61.

(b) The BAT shall instruct the employee not to eat, drink, put any object or substance in his or her mouth, and, to the extent possible, not belch during a waiting period before the confirmation test. This time period begins with the completion of the screening test, and shall not be less than 15 minutes. The confirmation test shall be conducted within 20 minutes of the completion of the screening test. The BAT shall explain to the employee the reason for this requirement (i.e., to prevent any accumulation of mouth alcohol leading to an artificially high reading) and the fact that it is for the employee's benefit. The BAT shall also explain that the test will be conducted at the end of the waiting period, even if the employee has disregarded the instruction. If the BAT becomes aware that the employee has not complied with this instruction, the BAT shall so note in the "Remarks" section of the form.

(c) (1) If a BAT other than the one who conducted the screening test is conducting the confirmation test, the new BAT shall initiate a new Breath Alcohol Testing form. The BAT shall complete Step 1 on the form. The employee shall then complete Step 2 on the form, signing the certification. Refusal by the employee to sign this certification shall be regarded as a refusal to take the test. The BAT shall note in the "Remarks" section of the form that a different BAT conducted the screening test.

(2) In all cases, the procedures of § 40.63 (a), (b), and (c) shall be followed. A new mouthpiece shall be used for the confirmation test.

(d) Before the confirmation test is administered for each employee, the BAT shall ensure that the EBT registers 0.00 on an air blank. If the reading is greater than 0.00, the BAT shall conduct

one more air blank. If the reading is greater than 0.00, testing shall not proceed using that instrument. However, testing may proceed on another instrument.

(e) Any EBT taken out of service because of failure to perform an air blank accurately shall not be used for testing until a check of external calibration is conducted and the EBT is found to be within tolerance limits.

(f) In the event that the screening and confirmation test results are not identical, the confirmation test result is deemed to be the final result upon which any action under operating administration rules shall be based.

(g) (1) If the EBT provides a printed result, but does not print the results directly onto the form, the BAT shall show the employee the result displayed on the EBT. The BAT shall then affix the test result printout to the breath alcohol test form in the designated space, using a method that will provide clear evidence of removal (e.g., tamper-evident tape).

(2) If the EBT prints the test results directly onto the form, the BAT shall show the employee the result displayed on the EBT.

(h) (1) Following the completion of the test, the BAT shall date the form and sign the certification in Step 3 of the form. The employee shall sign the certification and fill in the date in Step 4 of the form.

(2) If the employee does not sign the certification in Step 4 of the form or does not initial the log book entry for a test, it shall not be considered a refusal to be tested. In this event, the BAT shall note the employee's failure to sign or initial in the "Remarks" section of the form.

(3) If a test result printed by the EBT (see paragraph (g)(1) or (g)(2) of this section) does not match the displayed result, the BAT shall note the disparity in the remarks section. Both the employee and the BAT shall initial or sign the notation. In accordance with § 40.79, the test is invalid and the employer and employee shall be so advised.

(4) The BAT shall conduct an air blank. If the reading is greater than 0.00, the test is invalid.

(i) The BAT shall transmit all results to the employer in a confidential manner.

(1) Each employer shall designate one or more employer representatives for the purpose of receiving and handling alcohol testing results in a confidential manner. All communications by BATs to the employer concerning the alcohol testing results of employees shall be to a designated employer representative.

(2) Such transmission may be in writing, in person or by telephone or electronic means, but the BAT shall ensure immediate transmission to the employer of results that require the employer to prevent the employee from performing a safety-sensitive function.

(3) If the initial transmission is not in writing (e.g., by telephone), the employer shall establish a mechanism to verify the identity of the BAT providing the information.

(4) If the initial transmission is not in writing, the BAT shall follow the initial transmission by providing to the employer the employer's copy of the breath alcohol testing form. The employer shall store the information so as to ensure that confidentiality is maintained as required by § 40.81.

§ 40.67 Refusals to test and uncompleted tests.

(a) Refusal by an employee to complete and sign the breath alcohol testing form (Step 2), to provide breath, to provide an adequate amount of breath, or otherwise to cooperate with the testing process in a way that prevents the completion of the test, shall be noted by the BAT in the remarks section of the form. The testing process shall be terminated and the BAT shall immediately notify the employer.

(b) If a screening or confirmation test cannot be completed, or if an event occurs that would invalidate the test, the BAT shall, if practicable, begin a new screening or confirmation test, as applicable, using a new breath alcohol testing form with a new sequential test number (in the case of a screening test conducted on an EBT that meets the requirements of § 40.53(b) or in the case of a confirmation test).

§ 40.69 Inability to provide an adequate amount of breath.

(a) This section sets forth procedures to be followed in any case in which an employee is unable, or alleges that he or she is unable, to provide an amount of breath sufficient to permit a valid breath test because of a medical condition.

(b) The BAT shall again instruct the employee to attempt to provide an adequate amount of breath. If the employee refuses to make the attempt, the BAT shall immediately inform the employer.

(c) If the employee attempts and fails to provide an adequate amount of breath, the BAT shall so note in the "Remarks" section of the breath alcohol testing form and immediately inform the employer.

(d) If the employee attempts and fails to provide an adequate amount of breath, the employer shall proceed as follows:

(1) [Reserved]

(2) The employer shall direct the employee to obtain, as soon as practical after the attempted provision of breath, an evaluation from a licensed physician who is acceptable to the employer concerning the employee's medical ability to provide an adequate amount of breath.

(i) If the physician determines, in his or her reasonable medical judgment, that a medical condition has, or with a high degree of probability, could have, precluded the employee from providing an adequate amount of breath, the employee's failure to provide an adequate amount of breath shall not be deemed a refusal to take a test. The physician shall provide to the employer a written statement of the basis for his or her conclusion.

(ii) If the licensed physician, in his or her reasonable medical judgment, is unable to make the determination set forth in paragraph (d)(2)(i) of this section the employee's failure to provide an adequate amount of breath shall be regarded as a refusal to take a test. The licensed physician shall provide a written statement of the basis for his or her conclusion to the employer.

§§ 40.71-40.77 [Reserved]

§ 40.79 Invalid tests.

(a) A breath alcohol test shall be invalid under the following circumstances:

(1) The next external calibration check of an EBT produces a result that differs by more than the tolerance stated in the QAP from the known value of the test standard. In this event, every test result of 0.02 or above obtained on the device since the last valid external calibration check shall be invalid;

(2) The BAT does not observe the minimum 15-minute waiting period prior to the confirmation test, as provided in § 40.65(b);

(3) The BAT does not perform an air blank of the EBT before a confirmation test, or an air blank does not result in a reading of 0.00 prior to or after the administration of the test, as provided in § 40.65;

(4) The BAT does not sign the form as required by §§ 40.63 and 40.65;

(5) The BAT has failed to note on the remarks section of the form that the employee has failed or refused to sign the form following the recording or printing on or attachment to the form of the test result;

(6) An EBT fails to print a confirmation test result; or

(7) On a confirmation test and, where applicable, on a screening test, the sequential test number or alcohol concentration displayed on the EBT is not the same as the sequential test number or alcohol concentration on the printed result.

(b) [Reserved]

§ 40.81 Availability and disclosure of alcohol testing information about individual employees.

(a) Employers shall maintain records in a secure manner, so that disclosure of information to unauthorized persons does not occur.

(b) Except as required by law or expressly authorized or required in this section, no employer shall release covered employee information that is contained in the records required to be maintained by this part or by DOT agency alcohol misuse rules.

(c) An employee subject to testing is entitled, upon written request, to obtain copies of any records pertaining to the employee's use of alcohol, including any records pertaining to his or her alcohol tests. The employer shall promptly provide the records requested by the employee. Access to an employee's records shall not be contingent upon payment for records other than those specifically requested.

(d) Each employer shall permit access to all facilities utilized in complying with the requirements of this part and DOT agency alcohol misuse rules to the Secretary of Transportation, any DOT agency with regulatory authority over the employer, or a state agency with regulatory authority over the employer (as authorized by DOT agency regulations).

(e) When requested by the Secretary of Transportation, any DOT agency with regulatory authority over the employer, or a state agency with regulatory authority over the employer (as authorized by DOT agency regulations), each employer shall make available copies of all results for employer alcohol testing conducted under the requirements of this part and any other information pertaining to the employer's alcohol misuse prevention program. The information shall include name-specific alcohol test results, records and reports.

(f) When requested by the National Transportation Safety Board as part of an accident investigation, an employer shall disclose information related to the employer's administration of any post-accident alcohol tests administered following the accident under investigation.

(g) An employer shall make records available to a subsequent employer upon receipt of a written request from a covered employee. Disclosure by the subsequent employer is permitted only as expressly authorized by the terms of the employee's written request.

(h) An employer may disclose information required to be maintained under this part pertaining to a covered employee to that employee or to the decisionmaker in a lawsuit, grievance, or other proceeding initiated by or on behalf of the individual, and arising from the results of an alcohol test administered under the requirements of this part, or from the employer's determination that the employee engaged in conduct prohibited by a DOT agency alcohol misuse regulation (including, but not limited to, a worker's compensation, unemployment compensation, or other proceeding relating to a benefit sought by the employee).

(i) An employer shall release information regarding a covered employee's records as directed by the specific, written consent of the employee authorizing release of the information to an identified person. Release of such information is permitted only in accordance with the terms of the employee's consent.

§ 40.83 Maintenance and disclosure of records concerning EBTs and BATs.

(a) Each employer or its agent shall maintain the following records for two years:

(1) Records of the inspection and maintenance of each EBT used in employee testing;

(2) Documentation of the employer's compliance with the QAP for each EBT it uses for alcohol testing under this part;

(3) Records of the training and proficiency testing of each BAT used in employee testing;

(4) The log books required by § 40.59(c).

(b) Each employer or its agent shall maintain for five years records pertaining to the calibration of each EBT used in alcohol testing under this part, including records of the results of external calibration checks.

(c) Records required to be maintained by this section shall be disclosed on the same basis as provided in § 40.81.

Appendix A to Subpart C of Part 40—The Breath Alcohol Testing Form

BILLING CODE 4910-82-U

U.S. Department of Transportation (DOT) Breath Alcohol Testing Form

[THE INSTRUCTIONS FOR COMPLETING THIS FORM ARE ON THE BACK OF COPY 3]

► STEP 1: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

A. Employee Name _____
(PRINT) (First, M.I., Last)

B. SSN or Employee ID No. _____

C. Employer Name, _____
Address, & _____
Telephone No. _____

() _____
Telephone Number

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post-accident ☐ Return to Duty ☐ Follow-up

► STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to breath alcohol testing required by U.S. Department of Transportation regulations and that the identifying information provided on this form is true and correct.

Signature of Employee

_____/_____/_____
Date Month Day Year

► STEP 3: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

I certify that I have conducted breath alcohol testing on the above named individual in accordance with the procedures established in the U.S. Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing devices identified, and that the results are as recorded.

Screening test: Complete only if the testing device is not designed to print the following.

Test No.	Testing Device Name	Testing Device Serial Number	Time	AM PM	Result

Confirmation test: Confirmation test results MUST be affixed to the back of each copy of this form.

Remarks: _____

(PRINT) Breath Alcohol Technician's Name (First, M.I., Last)

Signature of Breath Alcohol Technician

_____/_____/_____
Date Month Day Year

► STEP 4: TO BE COMPLETED BY EMPLOYEE

I certify that I have submitted to breath alcohol testing and the results are as recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment if the results are 0.02 or greater.

Signature of Employee

_____/_____/_____
Date Month Day Year

AFFIX SCREENING TEST RESULTS HERE
(IF APPLICABLE)

USE TAMPER-EVIDENT TAPE

AFFIX CONFIRMATION TEST RESULTS HERE

USE TAMPER-EVIDENT TAPE

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information is estimated for each respondent to average: 1 minute/employee, 4 minutes/Breath Alcohol Technician. Individuals may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to U.S. Department of Transportation, Drug Enforcement and Program Compliance, Room 9404, 400 Seventh St., SW, Washington, D.C. 20590 or Office of Management and Budget, Paperwork Reduction Project, Room 3001, 725 Seventeenth St., NW, Washington, D.C. 20503.

COPY 1 - ORIGINAL - BREATH ALCOHOL TECHNICIAN RETAINS

U.S. Department of Transportation (DOT) Breath Alcohol Testing Form

[THE INSTRUCTIONS FOR COMPLETING THIS FORM ARE ON THE BACK OF COPY 3]

STEP 1: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

A. Employee Name _____
(PRINT) (First, M.I., Last)

B. SSN or Employee ID No. _____

C. Employer Name, _____
Address, & _____
Telephone No. _____

()
Telephone Number _____

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post-accident ☐ Return to Duty ☐ Follow-up

STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to breath alcohol testing required by U.S. Department of Transportation regulations and that the identifying information provided on this form is true and correct.

Signature of Employee

Date _____ / _____ / _____
Month Day Year

STEP 3: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

I certify that I have conducted breath alcohol testing on the above named individual in accordance with the procedures established in the U.S. Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing devices identified, and that the results are as recorded.

Screening test: Complete only if the testing device is not designed to print the following.

Test No.	Testing Device Name	Testing Device Serial Number	Time	AM PM	Result
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Confirmation test: Confirmation test results MUST be affixed to the back of each copy of this form.

Remarks: _____

(PRINT) Breath Alcohol Technician's Name (First, M.I., Last)

Signature of Breath Alcohol Technician

Date _____ / _____ / _____
Month Day Year

STEP 4: TO BE COMPLETED BY EMPLOYEE

I certify that I have submitted to breath alcohol testing and the results are as recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment if the results are 0.02 or greater.

Signature of Employee

Date _____ / _____ / _____
Month Day Year

COPY 2 - EMPLOYEE RETAINS

OMB No. 2105-0529

**AFFIX SCREENING TEST RESULTS HERE
(IF APPLICABLE)**

USE TAMPER-EVIDENT TAPE

AFFIX CONFIRMATION TEST RESULTS HERE

USE TAMPER-EVIDENT TAPE

Privacy Act Statement

(applicable in those cases where completed Breath Alcohol Testing Forms are retained in a Federal Privacy Act system of records)

Except for your Social Security Number (SSN), submission of the information on the front side of this form is mandatory. Incomplete submission of the information, failure to provide an adequate breath specimen for testing without a valid medical explanation, engaging in conduct that clearly obstructs the testing process, or failure to sign the certification statements on the front side of this form may result in delay or denial of your application for employment/appointment, your inability to resume performing safety-sensitive duties, removal from a safety-sensitive position, or other disciplinary action.

The authority for obtaining the breath specimen required by the U.S. Department of Transportation is the Omnibus Transportation Employee Testing Act of 1991, Pub. L. 102-143, Title V. The principal purpose for which the information sought is to be used is to ensure that you have submitted to breath alcohol testing and to ensure that you are promptly notified in the event of noncompliance with the U.S. Department of Transportation breath alcohol testing requirements.

Submission of your SSN is not required by law and is voluntary. If you object to the use of your SSN in this form, you will not be denied any right, benefit, or privilege provided by law; a substitute number or other identifier will be assigned.

The information provided in this form may be disclosed, as a routine use, to a Federal, State, or local agency for authorized investigative or enforcement purposes or to a court or an administrative tribunal when the Government or one of its agencies is a party to a judicial proceeding before the court or involved in administrative proceedings before the tribunal.

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information is estimated for each respondent to average: 1 minute/employee, 4 minutes/Breath Alcohol Technician. Individuals may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to U.S. Department of Transportation, Drug Enforcement and Program Compliance, Room 9404, 400 Seventh St., SW, Washington, D.C. 20590 or Office of Management and Budget, Paperwork Reduction Project, Room 3001, 725 Seventeenth St., NW, Washington, D.C. 20503.

COPY 2 - EMPLOYEE RETAINS

U.S. Department of Transportation (DOT) Breath Alcohol Testing Form

[THE INSTRUCTIONS FOR COMPLETING THIS FORM ARE ON THE BACK OF COPY 3]

STEP 1: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

A. Employee Name _____
(PRINT) (First, M.I., Last)

B. SSN or Employee ID No. _____

C. Employer Name, _____
Address, & _____
Telephone No. _____

() Telephone Number

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post-accident ☐ Return to Duty ☐ Follow-up

STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to breath alcohol testing required by U.S. Department of Transportation regulations and that the identifying information provided on this form is true and correct.

Signature of Employee

Date ____/____/____
Month Day Year

STEP 3: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

I certify that I have conducted breath alcohol testing on the above named individual in accordance with the procedures established in the U.S. Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing devices identified, and that the results are as recorded.

Screening test: Complete only if the testing device is not designed to print the following.

Test No.	Testing Device Name	Testing Device Serial Number	Time	AM PM	Result
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Confirmation test: Confirmation test results **MUST** be affixed to the back of each copy of this form.

Remarks: _____

(PRINT) Breath Alcohol Technician's Name (First, M.I., Last)

Signature of Breath Alcohol Technician

Date ____/____/____
Month Day Year

STEP 4: TO BE COMPLETED BY EMPLOYEE

I certify that I have submitted to breath alcohol testing and the results are as recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment if the results are 0.02 or greater.

Signature of Employee

Date ____/____/____
Month Day Year

COPY 3 - FORWARD TO THE EMPLOYER

OMB No. 2105-0529

**AFFIX SCREENING TEST RESULTS HERE
(IF APPLICABLE)**

USE TAMPER-EVIDENT TAPE

AFFIX CONFIRMATION TEST RESULTS HERE

USE TAMPER-EVIDENT TAPE

INSTRUCTIONS FOR COMPLETING THE U.S. DEPARTMENT OF TRANSPORTATION BREATH ALCOHOL TESTING FORM

NOTE: Use a ballpoint pen, press hard, and check all copies for legibility.

STEP 1 The Breath Alcohol Technician (BAT) completes the information required in this step. Be sure to print the employee's name and check the box identifying the reason for the test.

NOTE: If the employee refuses to provide SSN or I.D. number, be sure to indicate this in the remarks section in STEP 3. Proceed with STEP 2.

STEP 2 Instruct the employee to read, sign, and date the employee certification statement in STEP 2.

NOTE: If the employee refuses to sign the certification statement, do not proceed with the alcohol test. Contact the designated employer representative.

STEP 3 The Breath Alcohol Technician (BAT) completes the information required in this step. After conducting the alcohol screening test, do the following (as appropriate):

If the breath testing device used in conducting the screening test is not capable of printing the screening test information located on the front of this form (test number, testing device name, testing device serial number, time of test and results), complete this information in the space provided on the front of this form.

NOTE: Be sure to enter the result of the test exactly as it is indicated on the breath testing device, i.e., 0.00, 0.02, 0.04, etc.

OR. If the breath testing device used in conducting the screening test is capable of printing the screening test information located on the front of this form, affix the printed information in the space provided above. Be sure to use tamper-evident tape.

If the results of the screening test are less than 0.02, print, sign your name, and enter today's date in the space provided. Go to STEP 4.

If the results of the screening test are 0.02 or greater, a confirmation test must be administered in accordance with DOT regulations. An **EVIDENTIAL BREATH TESTING** device that is capable of printing confirmation test information must be used in conducting this test.

After conducting the alcohol confirmation test, affix the printed information in the space provided above. Be sure to use tamper-evident tape.

Print, sign your name, and enter the date in the space provided. Go to STEP 4.

STEP 4 Instruct the employee to read, sign, and date the employee certification statement in STEP 4.

NOTE: If the employee refuses to sign the certification statement in STEP 4, be sure to indicate this in the remarks section in STEP 3.

Retain Copy 1 (white page) for BAT records.

Give Copy 2 (green page) to the employee.

Forward Copy 3 (blue page) to the employer.

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information is estimated for each respondent to average: 1 minute/employee, 4 minutes/Breath Alcohol Technician. Individuals may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to U.S. Department of Transportation, Drug Enforcement and Program Compliance, Room 9404, 400 Seventh St., SW, Washington, D.C. 20590 or Office of Management and Budget, Paperwork Reduction Project, Room 3601, 725 Seventeenth St., NW, Washington, D.C. 20503.

COPY 3 - FORWARD TO THE EMPLOYER

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket 49384, Notice 94-3]

RIN 2105-AB95

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: Under the Omnibus Transportation Employee Testing Act of 1991, the Department of Transportation is required to implement alcohol testing programs in various transportation industries. This proposed rule would establish circumstances in which blood alcohol testing could be used in these programs and procedures that would be used for blood alcohol testing.

DATES: Comments on this notice of proposed rulemaking should be received by May 16, 1994. Late-filed comments will be considered to the extent practicable.

ADDRESSES: Comments should be sent to Docket Clerk, Att: Docket No. 49384, Department of Transportation, 400 7th Street, SW., room 4107, Washington DC, 20590. For the convenience of persons wishing to review the docket, it is requested that comments be sent in duplicate. Persons wishing their comments to be acknowledged should enclose a stamped, self-addressed postcard with their comment. The docket clerk will date stamp the postcard and return it to the sender. Comments may be reviewed at the above address from 9 a.m. through 5:30 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Donna Smith, Acting Director, Department of Transportation Office of Drug Enforcement and Program Compliance, 400 7th Street, SW., Washington DC, 20590, room 9404, 202-366-3784; or Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, 400 7th Street, SW., room 10424, 202-366-9306.

SUPPLEMENTARY INFORMATION: Department published in today's Federal Register a final rule (49 CFR part 40) establishing testing procedures for the Department's new alcohol testing rules. The Department's December 1992 NPRM for these procedures did not propose to permit blood alcohol testing. Therefore, it did not include any proposed blood alcohol testing procedures. Today's NPRM proposes limited circumstances in which blood

alcohol testing would be permitted for the covered operating administrations and procedures that would be used for this purpose. We seek comments on these proposed procedures and on any additions, deletions, or modifications we should make to them. In addition, we seek comment on the broader question of whether the Department should adopt blood alcohol testing at all.

Section-by-Section Analysis

Section 40.71 Authorized Uses for Blood Alcohol Testing

We propose to allow blood alcohol testing only in a limited set of circumstances. Blood alcohol testing could be used in reasonable suspicion and post-accident testing, where an evidential breath testing device (EBT) is not readily available, and in place of a medical evaluation in "shy lung" situations. If breath testing were not readily available for a reasonable suspicion or post-accident test, employers would have to use blood alcohol testing to meet their regulatory obligations.

We are aware of certain advantages to blood alcohol testing. It is accurate, does not require expenditures for expensive new equipment, and can be conducted by qualified personnel who are generally readily available even in remote locations. At the same time, blood alcohol testing has a number of disadvantages, all of which are exacerbated with extensive use. It is the most intrusive form of testing, it does not provide an immediate confirmed result, and it necessitates additional procedural complexities such as collection, laboratory, and chain of custody requirements. There could be additional costs and litigation. Nevertheless, because we are aware that, in some circumstances the unavailability of EBTs meeting part 40 requirements may make breath testing impracticable, we believe that it may be useful to allow some flexibility. We think it better, in these circumstances, to allow testing using a method with some disadvantages than to be unable to complete a test at all.

Reasonable suspicion and post-accident tests are more likely than other kinds of test to happen at unpredictable times and in remote locations. (The time and, to some extent, place of random and pre-employment testing are more likely to be under the employer's control.) Consequently, as commenters suggested, unless an employer incurs the expense of having EBTs in all of its locations, or has an extensive rapid-deployment capability, it may be

substantially easier and less costly to arrange for a blood alcohol test in these circumstances. In some cases, it may be impossible to get an EBT to a remote location in time to conduct a meaningful test.

Particularly in remote locations, there could be situations in which the only person trained to conduct alcohol tests is the supervisor of an employee subject to a post-accident or reasonable suspicion test. Our current rules permit a supervisor to conduct breath alcohol tests, if the supervisor is a trained BAT and another BAT is not available, as long as operating administration rules do not prohibit this action by the supervisor. In the case of reasonable suspicion tests, the operating administration rules prohibit the supervisor who has made the reasonable suspicion determination from conducting either the screening or confirmation test. The purpose of this NPRM is to increase flexibility in post-accident and reasonable suspicion testing in circumstances in which testing would otherwise be difficult to accomplish. With that purpose in mind, would it make sense to permit supervisors to conduct screening tests in these situations? Should blood testing be treated any differently from breath testing for these purposes?

Moreover, the number of post-accident and reasonable suspicion tests is likely to be substantially lower than the numbers of pre-employment and random tests. This means that the disadvantages of blood alcohol testing noted above will occur in a limited number of cases. (The Department estimates that there will be around 2500 blood alcohol tests per year under this proposal and seeks comment on whether this estimate is reasonable.) If employers "stand down" employees on the basis of the event leading to the test, the safety impact of the lack of an immediate result may be further reduced.

One of the key conditions for allowing the use of blood alcohol testing is that EBTs not be "readily available." Because of its greater invasiveness and because it does not produce an immediate result, the use of blood alcohol testing is intended to be used only in those reasonable suspicion and post-accident testing circumstances where it is not practicable to use breath testing. Blood alcohol testing is not intended, under the proposal, to be an equal alternative method that an employer can choose as a matter of preference.

We seek comment on when the final rule should regard an EBT as being "readily available." For example, if a

breath test can be arranged within a given time (e.g., two hours) of the event requiring the test, should breath testing be regarded as readily available? What should the time frame be? What if the cost of obtaining an EBT and bringing it to the site for testing is a certain multiple of the cost of conducting blood alcohol testing in that case? What if it were simply more convenient or less expensive to use a blood alcohol test rather than breath testing in a particular case? Are there other criteria that could be used to determine when breath testing was readily available? Should this be left to the judgment of the employer? If so, how would the Department judge when this discretion had been exercised properly? Should the Department require the employer to document the facts that led to a decision to use blood alcohol testing?

In context of this discussion of "readily available," we would point out that the EBT involved need not be one that the employer owns. It could also be a device that is owned by another employer or a third-party provider. We do not think that it should be necessary for an employer to pre-position an EBT (or enter into a contract) at every possible testing location. However, we do believe it is fair to expect employers to make arrangements for the use of EBTs either through purchase, lease or contract, assuming normal deployment to do routine random and pre-employment testing. The Department seeks comment on whether, and how, these expectations should be made part of the text of the final rule.

The NPRM proposes that, if no EBT were readily available for even the screening test, a blood sample would be collected and sent to the laboratory, where two tests would be conducted on the primary specimen. Alternatively, if an EBT were available for the screening test, but an EBT meeting part 40 requirements for use in a confirmation test were not available, a blood confirmation test could be performed. Some questions arise about the former situation. Would this provision discourage employers from obtaining the less expensive alcohol screening devices permitted by part 40? Would employers be deterred from using blood as a collection method by fear of confrontations with or litigation by employees who resented the intrusiveness of blood alcohol testing all the more for the absence of a breath screening test? Would additional supervisor training be needed? On the other hand, would the majority of situations in which blood could be used under this proposal likely be situations in which no EBTs at all were available,

so that using blood for both screening and confirmation testing would be necessary in order to make the proposal meaningful?

The NPRM also proposes that employers could use blood alcohol testing for an employee covered under the "shy lung" provision of the Department's new alcohol testing procedures. If an employee was unable to provide sufficient breath for a breath test, the employer could choose either to refer the employee for a medical evaluation or to draw a blood sample as provided in this NPRM.

Whether for liability reasons or on the basis of the events leading to a post-accident or reasonable suspicion test, many employers might prefer to "stand down" the employee pending the receipt of the laboratory result of the blood alcohol test. Is it necessary for the Department's regulations to address this subject? If so, what should the rules provide?

Section 40.73 Collection Procedures for Blood Alcohol Tests

We think it will not be necessary to establish extensive new procedures for collecting blood samples, given the limited circumstances in which use of this method would be authorized. (The situation would probably be different if blood testing were being proposed for pre-employment and random testing as well.) Collection of blood specimens for forensic purposes such as law enforcement is considered standard procedure at many medical facilities. For these reasons, we believe that we should depend, to the extent possible, on existing resources and programs. We propose that anyone who is licensed, certified, or otherwise authorized under state law to draw blood could do so in the State for purposes of the DOT program. In most states, physicians, nurses, phlebotomists, and sometimes other medical personnel, have this authority.

It is our understanding that states, for law enforcement and other forensic purposes, have approved procedures for collecting blood specimens for the purpose of alcohol testing. Except to the extent that DOT rules specify certain requirements, the NPRM would allow a blood specimen to be collected for purposes of the DOT program in accordance with these existing state procedures. As with personnel qualifications and specimen collection procedures, chain of custody requirements would follow state requirements for law enforcement and other forensic blood collections. The Department seeks comment on whether reliance on state requirements would

produce too much confusion or inconsistency, such that nationwide, uniform DOT procedures would be preferable. On the other hand, would such uniform DOT procedures make it too difficult to operate a blood testing program for a relatively small number of samples, reducing flexibility that this proposal is designed to permit?

The NPRM would require 20 ml of blood to be drawn for the test. As explained in the preamble to the final rule for part 40 published today, there is a statutory requirement for collecting split samples of body fluids in FAA, FTA, FRA, and FHWA programs. In this situation, the sample would be subdivided into two 10 ml tubes. Collections under the RSPA rule, where split samples are not required, would require only 10 ml of blood, placed in one tube. The NPRM would require certain standard testing materials to be used, which would be provided by testing laboratories in a sealed kit. The kit would include the blood tubes, labels, chain of custody form, blood extraction device, and swab. We seek comment on whether it is advisable to require the inclusion of blood extraction devices. That is, is including these materials needed, in light of the resources available at testing sites? Would including them give rise to concerns about theft? We also seek comment on whether the kit should also include standardized collection instructions. The employer would be responsible for ensuring the kit was available at the testing location.

Section 40.75 Laboratories for Blood Alcohol Testing

The regulatory text of this proposed section is a place-holder. One of the most difficult questions facing the Department is how to ensure that appropriately well-qualified laboratories test blood specimens for alcohol. Absent a satisfactory answer to this question, the viability of this proposed rule is in question.

One approach the Department could take, which is consistent with the approach of using existing resources to the extent practicable, is to rely on those laboratories—whether state-operated or private—that conduct forensic blood alcohol tests for law enforcement and other purposes in each state. The final rule would assume, in effect, that a laboratory whose findings were deemed sufficient under state law to act as the basis for criminal or civil penalties against persons in DUI or similar cases was adequate for DOT workplace testing program purposes. In order for this approach to work, there would have to be state or state-approved laboratories in

a sufficient number of states that had the willingness and capacity to accept and process "DOT" blood specimens. We see no reason why laboratories in every state would necessarily have to participate. Since we expect few blood alcohol tests, large numbers of laboratories would not be necessary, and specimens could be sent to a laboratory in any state that accepts commercial business. The Department seeks comments on the capacity and suitability of such laboratories.

A second approach would be to construct a system based on the laboratories certified by the Department of Health and Human Services (DHHS) for urine drug testing. DHHS has carefully reviewed the overall proficiency and forensic capability of these laboratories, and they are available to users throughout the country. Many DHHS-certified laboratories currently perform blood alcohol testing, but there is no blood alcohol testing proficiency requirement involved with DHHS certification. Under this approach, the Department, in cooperation with DHHS, could develop a proficiency requirement for blood alcohol testing. Such a requirement could be implemented through a DOT-DHHS agreement calling for DHHS certification and inspection for blood alcohol testing purposes.

This approach would require DOT and DHHS to work out an agreement. The cost of the certification program—both to the Department and to laboratories—is not yet known, though the Department is working with DHHS to develop this information. The cost to the Federal government of this certification program would have to be recovered from the laboratories via user fees. Given the small number of tests, it is questionable whether laboratories would find it cost-effective to become certified for blood alcohol testing, though there could be some pressure from customers to process blood as well as urine samples. The Department seeks comments on the advantages and disadvantages of this approach.

There are other possibilities. For example, the Department could use laboratories certified by private certifying bodies, though the Department has expressly declined to do so in its drug testing program. DOT and DHHS both believe that the DHHS approval process for laboratories provides a more thorough and intense review of laboratory quality than existing private certification programs. The Department could also contract with one or more laboratories to conduct the needed tests. It is likely that user fees would be needed to fund such

an approach. The Department seeks comment on any additional approaches that commenters believe have merit.

This discussion of the need for laboratory certification is in the context of a testing program that does not provide for evidentiary proceedings in which an individual could challenge test results. Existing Coast Guard alcohol testing regulations provide for post-accident blood testing in some situations. The validity of these proceedings is subject to evidentiary hearings, has long been recognized in administrative and court decisions, and is not brought into question by the Department's proposals concerning laboratory certification.

Section 40.77 Testing of Blood Specimens

The basic scheme of this provision is similar to the process the laboratory uses for drug testing. An aliquot of the primary specimen is tested by gas chromatography (GC) or enzyme assay. (Because testing for alcohol is simpler chemically than testing for drug metabolites, mass spectrometry is not needed.) If the alcohol concentration is less than 0.04, the laboratory reports a negative test to the employer. If the result is 0.04 or above, then the laboratory conducts a GC test on a second aliquot of the primary specimen. If the alcohol concentration is less than 0.04, the laboratory reports a negative test to the employer. If the result is 0.04 or above, the laboratory reports the quantitative (positive) result to the employer.

The split sample procedure also operates in an analogous way to the drug testing procedures. If the employee requests a test of the split specimen within 72 hours of being informed of the positive result, the employer tells the laboratory to send the split specimen to a second laboratory, which runs a single GC test on the split specimen. As under the drug testing procedures, the employee would have the opportunity to present evidence that he or she had been unable to make the request within the 72-hour time frame. If the result is 0.04 or above, the positive test result stands. If the result is less than 0.04, the test result is invalid. The consequences of the test result would not be stayed pending the test of the split specimen; the employee would remain barred from performing safety-sensitive functions pending the receipt of the analysis of the split specimen, unless the employee had met the conditions in the applicable operating administration rule for return to duty.

Because the time when one could gain a safety benefit from removing from

safety-sensitive functions an employee testing between 0.02 and .039 will long since have passed, these procedures do not call for taking any action with respect to a test result in this range. The Department seeks comment on whether this approach makes sense and on whether there are any reasons to report such results to the employer. The Department also notes that the proposed procedure calls for two tests to be conducted on the primary specimen even if there has been a screening test on a preliminary EBT. The reason for this requirement is to avoid confusion at the laboratory by requiring a standard procedure in all cases, even where one of the two tests is, strictly speaking, unnecessary. The Department also seeks comment on this proposal.

Section 40.79(b) Invalid Tests

This paragraph would be added to the existing list of fatal flaws for breath alcohol tests. It would spell out those actions that would automatically cause a test to be deemed invalid. The paragraph is intended to provide protections for the accuracy of the process equivalent to those provided for breath alcohol testing and urine drug testing.

We seek comment on whether it should be a fatal flaw if an unauthorized person has succeeded in drawing a blood sample from an employee. Once the sample has been drawn, does the lack of authorization of the individual drawing the sample affect its accuracy? Should this be a fatal flaw simply as a means of ensuring that appropriately qualified people draw blood, regardless of the effects on sample accuracy?

In some circumstances, it may be unclear to the personnel involved what state a test occurs in (e.g., a post-accident test on a bridge between two states). The procedures of the two states may differ. Should the rule be modified to avoid the invalidation of a test just because the procedures used turned out to pertain to the wrong state?

Regulatory Analyses and Notices

Because of substantial public interest and substantial impacts on a wide range of private and public sector organizations, the Department has determined that this proposed rule—in conjunction with the operating administrations' alcohol and drug testing rules and the remainder of the alcohol testing portion of part 40—is significant under Executive Order 12866. OMB has reviewed this NPRM under that Order. The NPRM is also significant under the Department's regulatory policies and procedures.

The Department has prepared a regulatory evaluation for the alcohol portion of part 40, which we have included in the docket. The costs of the application of part 40 procedures to the programs of the various operating administrations are estimated in each of the operating administrations' regulatory evaluations for their final alcohol rules being published today. At the time of a final rule based on this NPRM, the covered operating administrations will supplement their part 40 alcohol testing rule regulatory evaluations as needed with respect to blood alcohol testing.

The Department expects that this proposal, if implemented, will lower costs to employers by providing more flexibility and decreasing the number of EBTs needed. As noted above, the Department estimates that there would be about 2500 blood alcohol tests annually, under all five affected operating administration rules. The Department expects that the amount of employee time involved in drawing blood would be about the same time involved in breath testing. We seek comment on these matters.

This NPRM, in conjunction with the operating administration drug and alcohol testing rules, is likely to have a significant economic impact on a substantial number of small entities. These impacts are assessed in the operating administrations' supplements to their alcohol testing rule regulatory evaluations. The Federalism impacts of this rule are either minimal or required by statute; for these reasons, we have not prepared a Federalism assessment.

List of Subjects in 49 CFR Part 40

Drug testing, Reporting and recordkeeping requirements, Safety, Transportation.

Issued this 25th day of January 1994, at Washington, DC.

Federico Peña,
Secretary of Transportation.

David R. Hinson,
Administrator, Federal Aviation Administration.

Rodney E. Slater,
Administrator, Federal Highway Administration.

Jolene M. Molitoris,
Administrator, Federal Railroad Administration.

Gordon J. Linton,
Administrator, Federal Transit Administration.

Ana Sol Gutiérrez,
Acting Administrator, Research and Special Programs Administration.

For the reasons set forth in the preamble, the Department of Transportation proposes to amend title 49, Code of Federal Regulations, part 40, as follows:

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

1. The authority for part 40 is proposed to continue to read as follows:

Authority: 49 U.S.C. 102,301,322; 49 U.S.C. app. 1301nt., app. 1434nt., app. 2717, app. 1618a.

§ 40.3 [Amended]

2. In § 40.3 of part 40, the period following the end of the definition of "alcohol concentration" in section 40.3 is proposed to be removed, and the following words added: "or the blood alcohol concentration indicated by a blood alcohol test under this part." In the definition of "screening test," the words "(or, where authorized, blood)" are proposed to be added between the word "breath" and the word "specimen."

3. A new paragraph (d)(1) is proposed to be added to section 40.69, to read as follows:

§ 40.69 Inability to provide an adequate amount of breath.

* * * * *

(d) * * *

(1) The employer may direct the employee to submit to a blood alcohol test in accordance with the procedures of §§ 40.71 through 40.77; or

* * * * *

4. and 5. New sections §§ 40.71 through 40.77 are proposed to be added to subpart C of part 40, to read as follows:

§ 40.71 Authorized uses of blood alcohol testing.

Blood alcohol testing is authorized only in the following circumstances:

(a) When operating administration rules require a post-accident or reasonable suspicion test, and an EBT is not readily available for either screening or confirmation tests, blood alcohol testing shall be used for both screening and confirmation test purposes.

(b) When operating administration rules require a post-accident or reasonable suspicion test, and an EBT is readily available for the screening test but an EBT suitable for confirmation testing is not readily available, blood alcohol testing shall be used for confirmation test purposes.

(c) When the employee attempts and fails to provide an adequate amount of breath, blood alcohol testing may be used for both screening and confirmation test purposes.

§ 40.73 Collection procedures for blood alcohol tests.

(a) Personnel who conduct blood alcohol tests shall be licensed, certified, or otherwise authorized under state law to draw blood in the State in which the test takes place.

(b) The drawing of blood shall be conducted using a blood alcohol test kit containing the following items:

(1) Two evacuated gray-capped glass tubes (except that for a kit to be used only for testing under the Research and Special Programs Administration (RSPA) rule, there is required to be only one such tube);

(2) A chain of custody form;

(3) A label for each tube;

(4) A sterile, non-alcohol swab; and

(5) An appropriate, disposable blood extraction device.

(c) The employer shall use only a blood alcohol test kit obtained from a laboratory meeting the requirements of § 40.75. Employers shall use kits in accordance with the supplier's instructions, and shall not use a kit after its expiration date. Employers shall not re-use a blood extraction device.

(d) The drawing of blood shall be conducted in accordance with forensic blood alcohol collection procedures approved in the State in which the test takes place.

(e) (1) Except as provided in this paragraph, at least 20 ml of venous blood shall be drawn and subdivided into two equal portions of 10 ml each. The collector shall place each portion in a separate evacuated gray-capped tube, and label and seal the tubes. The collector shall designate one of the tubes as the primary specimen and the other as the split specimen.

(2) Blood samples collected pursuant to the RSPA alcohol testing rule are not required to be subdivided. For tests required by only the RSPA alcohol testing rule, the collector shall draw 10 ml of venous blood and place it in an evacuated gray-capped tube, and label and seal the tube.

(f) Blood specimens shall be shipped to the laboratory, together with documentation of the chain of custody meeting forensic standards acceptable under the law of the State in which the test takes place.

§ 40.75 Laboratories for blood alcohol testing.

Blood alcohol testing under this part shall be conducted only in laboratories where such testing is authorized by Department of Transportation regulations.

§ 40.77 Testing of blood specimens.

(a) When the split sample method has been used, the laboratory shall retain the tube designated as the split specimen in secure refrigerated storage, with the seal intact. If the seal on the tube designated as the primary specimen has been broken, or the primary specimen is otherwise unavailable for testing, the laboratory shall use the tube designated as the split specimen in its place.

(b) The laboratory shall analyze an aliquot of the primary (or sole) specimen for its alcohol concentration, using gas chromatography or an enzyme assay, at a cutoff level of 0.04. If the result of this analysis is an alcohol concentration of less than 0.04, the laboratory shall report the result of the test to the employer as negative. In this case, the laboratory may discard the split specimen. If the alcohol concentration is 0.04 or greater, the laboratory shall analyze a second aliquot of the primary specimen, using gas chromatography.

(c) If the result of the analysis of the second aliquot is an alcohol concentration of less than 0.04, the laboratory shall report the result of the test to the employer as negative. In this case, the laboratory may discard the split specimen.

(d) If the result of the analysis of the second aliquot is an alcohol concentration of 0.04 or greater, the laboratory shall report the quantitative result to the employer. In this case, where the split sample collection method has been used, the laboratory will retain the split specimen in secure

refrigerated or frozen storage, with the seal intact, for 60 days from the date the laboratory acquires the sample.

(e) (1) At the time the employer informs the employee that the employee's test result is 0.04 or greater, the employer shall inform the employee that the employee has 72 hours in which to request a test of the split specimen. If the employee requests a test of the split specimen within 72 hours, the employer shall direct the laboratory to release the split specimen for testing.

(2) If an employee has not contacted the employer within 72 hours, as provided in paragraph (e)(1) of this section, the employee may present to the employer information documenting that serious illness, injury, inability to contact the employer, lack of actual notice of the verified positive test, or other circumstances unavoidably prevented the employee from timely contacting the employer. If the employer concludes that there is a legitimate explanation for the employee's failure to contact the employer within 72 hours, the employer shall direct that the analysis of the split specimen be performed.

(3) Pending receipt of the result of the analysis of the split specimen, the employee shall not perform safety-sensitive functions, unless the employee has met conditions in the applicable operating administration rule for return to safety-sensitive functions following a test result of 0.04 or greater.

(4) The laboratory shall ship the split specimen, with seal intact, and with appropriate chain of custody documentation, to a second laboratory meeting the requirements of § 40.75. The second laboratory shall analyze the split specimen for its alcohol concentration, using gas chromatography, at a cutoff level of 0.04.

(5) If the result of the analysis of the split specimen is an alcohol concentration of 0.04 or above, the laboratory shall report to the employer that the result of the test of the primary specimen has been reconfirmed.

(6) If the result of this test is an alcohol concentration of less than 0.04, or if any of the circumstances set forth in § 40.79(b)(8) occur, the laboratory shall report to the employer that the result of the test of the primary specimen has not been reconfirmed, and therefore, the test is invalid.

6. A new paragraph (b) is proposed to be added to § 40.79, to read as follows:

§ 40.79 Invalid tests.

(b) A blood alcohol test shall be invalid under the following circumstances:

(1) The person who draws the blood sample from the employee is not authorized to do so under the law of the State in which the sample is drawn;

(2) The test was not conducted in accordance with forensic blood alcohol collection procedures approved in the State in which the test takes place;

(3) The chain of custody does not meet forensic standards acceptable under the law of the State in which the blood is drawn or there is a break in the chain of custody;

(4) The volume of the specimen used for the primary blood alcohol test (i.e., as distinct from the split specimen) is less than 10 ml; except that if, upon arrival at the laboratory, the specimen volume is not less than 8 ml, the laboratory may accept the specimen if the laboratory can ensure that sufficient volume will be available for testing and any necessary reanalyses for quality control;

(5) The seal on both specimens (or the only specimen) is broken or shows evidence of tampering;

(6) The test did not take place in a laboratory meeting the requirements of § 40.75.

(7) The testing methods prescribed in § 40.77(b) are not used;

(8) If, after an employee makes a timely request for a test of the split specimen under § 40.77(e)—

(i) The split specimen is unavailable for testing;

(ii) There is insufficient blood to permit a valid reconfirmation test to be conducted;

(iii) The seal on the tube containing the split specimen has been broken prior to testing at the second laboratory, or otherwise shows evidence of tampering;

(iv) The split specimen has not been retained in secure and refrigerated storage prior to being transmitted to the second laboratory;

(v) The inter-laboratory chain of custody is incomplete; or

(vi) The test of the split specimen fails to reconfirm the presence of alcohol at a level of at least 0.04.

[FR Doc. 94-2031 Filed 02-03-94; 1:00 pm]
BILLING CODE 4910-62-U

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[NHTSA Docket No. 94-004; Notice 1]

Highway Safety Programs; Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice; Request for comments.

SUMMARY: This notice proposes Model Specifications for the performance and testing of alcohol screening devices. These devices test for the presence of alcohol, and may use breath or other bodily fluids, such as saliva, to do so. NHTSA is proposing these specifications to support State laws that target youthful offenders (i.e., "zero tolerance" laws) and the Department of Transportation's regulations on Alcohol Misuse Prevention, and in recognition of industry efforts to develop new technologies (i.e., non-breath devices) that measure alcohol content from bodily fluids.

A Conforming Products List (CPL) will be published identifying the devices that meet NHTSA's Model Specifications. The CPL can serve as a guide for those interested in purchasing devices that screen for the presence of alcohol.

DATES: Comments must be received no later than April 18, 1994.

ADDRESSES: Comments should refer to the docket number and the number of this notice and be submitted (preferably in ten copies) to the Docket Section, room 5109, 400 Seventh Street, SW., Washington, DC 20590 (Docket hours are from 9:30 a.m. to 4 p.m.).

FOR FURTHER INFORMATION CONTACT: Ms. Lori A. Miller, Office of Alcohol and State Programs, NTS-21, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590. Telephone (202) 366-9835.

SUPPLEMENTARY INFORMATION: On December 14, 1984 (49 FR 48854), the National Highway Traffic Safety Administration (NHTSA) issued a notice converting the mandatory standards for breath alcohol testing devices (38 FR 30459) to Model Specifications. The notice indicated that the agency would continue to test evidential breath testing devices (EBTs) and would release its findings by publishing a Conforming Products List (CPL) to provide States that choose not to conduct their own testing with adequate information upon which to base their purchasing decisions. These

Model Specifications provided for EBTs to be tested at alcohol concentration levels of 0.000, 0.050, 0.101 and 0.151.

Since 1984, a number of States have amended their laws by lowering the alcohol level at which drivers are deemed to be impaired or enacted new laws targeting youthful offenders, including "zero tolerance" laws, which provide that it is an offense for a person under the age of 21 to drive with any alcohol concentration level above 0.00 (or in some cases above 0.01 or 0.02).

On December 15, 1992 (57 FR 59382), the U.S. Department of Transportation (DOT) published a Notice of Proposed Rulemaking (NPRM) proposing rules to implement the "Omnibus Transportation Employee Testing Act of 1991," which requires alcohol testing programs in the aviation, motor carrier, rail, and mass transit industries, in the interest of public safety. The Research and Special Programs Administration (RSPA) proposed similar regulations for the pipeline industry. In general, the NPRM proposed to prohibit covered employees from performing safety-sensitive functions when test results indicate alcohol concentration levels of 0.04 or greater. The NPRM proposed to apply slightly different consequences to employees having alcohol concentration levels of 0.02 or greater but less than 0.04.

To determine alcohol concentration, the NPRM proposed to use breath as measured by only those EBTs listed on NHTSA's CPL which are capable of providing a printed result, sequentially numbering the tests conducted, and distinguishing alcohol from acetone at the 0.02 BAC level.

DOT received comments in response to this rulemaking action recommending that if NHTSA's Model Specifications are to be used for the transportation workplace alcohol testing programs, the Model Specifications should be consistent with the requirements of the rules. They suggested, for example, that the Model Specifications which test devices at 0.000, 0.050, 0.101 and 0.151 BAC should be amended to test devices at the 0.020 and 0.040 BAC levels.

In light of the trend in the States toward lowering alcohol levels and to address the comments received in response to DOT's NPRM, NHTSA amended its Model Specifications for EBTs on September 17, 1993 (58 FR 48705), by changing the alcohol concentration levels at which instruments are evaluated. The amended Model Specifications provide for devices to be tested at 0.000, 0.020, 0.040, 0.080 and 0.160 BAC. Tests for the presence of acetone were also added in the revised Model Specifications. In

addition, the agency tested EBTs against the new Model Specifications and updated the CPL.

On October 15, 1993, Enzymatics, Inc., submitted a petition for reconsideration to NHTSA regarding the Notice published on September 17, 1993. The petitioner, a manufacturer of a saliva alcohol test, argued that NHTSA should establish a procedure for the inclusion on the CPL of devices other than breath alcohol devices. More specifically, the petitioner objected to the "exclusive reliance on EBTs" in DOT's proposed rules.

In a final rule published elsewhere in today's *Federal Register*, DOT amends its procedures for conducting urine drug testing and adds procedures for conducting alcohol testing in transportation workplaces (49 CFR Part 40). This final rule differs from the NPRM in a number of key respects. The final rule does require the use of breath testing devices listed on the CPL for EBTs. However, the final rule permits the use of portable EBTs that are on NHTSA's CPL as screening tests, provided confirmation tests are conducted using EBTs that are capable of providing a printed result, sequentially numbering the tests conducted and distinguishing alcohol from acetone at the 0.02 BAC level. In addition, the final rule indicates that NHTSA is publishing a separate notice in today's *Federal Register* proposing to adopt Model Specifications and a CPL that would permit additional alcohol testing devices to be used for screening purposes.

This *Federal Register* notice is the one to which the final rule refers. It proposes to establish Model Specifications for alcohol screening devices, which differ from the Model Specifications for Evidential Breath Testing devices in a number of important respects. These proposed Model Specifications are designed to test whether devices are suitable for screening, not evidential, purposes. In addition, they are designed to test the performance of devices that may use bodily fluids other than breath (such as saliva) to determine the presence of alcohol.

Under these proposed Model Specifications, an alcohol screening device is defined as a device that is used to detect the presence of 0.020 or more BAC. The Model Specifications propose that the test result may be indicated by numerical read-out or by other means, such as by the use of lights or color changes.

The Model Specifications propose that the device may measure any bodily fluid, but the output must be in blood

alcohol concentration (BAC) units. Further, the relationship between the bodily fluid being measured and BAC must be properly established so that a means for evaluating the device can be devised. The relationship between breath alcohol concentration (BrAC) and blood alcohol concentration (BAC) is well established, and several studies have been published establishing a relationship between BAC and saliva alcohol concentration.¹ Accordingly, the proposed Model Specifications specifically provide that blood, breath or saliva may be used.

In addition, these Model Specifications identify the proposed conversion factors for devices that use these bodily fluids. The conversion factors between blood and breath are commonly accepted. Based on the available literature, NHTSA believes it is appropriate to use a one-to-one conversion factor between blood and saliva, and has included this factor in these proposed Model Specifications. We request comments on the proposed use of this conversion factor.

NHTSA proposes that if a manufacturer intends to use any bodily fluid other than blood, breath, or saliva to determine the presence of alcohol, the relationship between that fluid's alcohol concentration and blood alcohol concentration must be established according to scientifically acceptable standards.

Under these proposed Model Specifications, alcohol screening devices would be tested at 0.008 and 0.032 BAC under normal laboratory conditions to determine their precision and accuracy at detecting the presence of 0.020 or more BAC (Test 1), and at 0.000 BAC to determine the performance of these devices when providing blank readings (Test 2). The .008 and .032 BAC levels were selected based on criteria for precision and accuracy that are equivalent to those used for EBTs. They require that devices perform at a level of accuracy within ± 0.005 of 0.020 BAC (thereby establishing target values within 0.015 and 0.025 BAC), and a level of precision

which yields a standard deviation not greater than 0.0042. To achieve a confidence rate of 95% in the results of these 20 tests, we propose to establish measurement points at 1.73 standard deviations (or 0.007 BAC) below and above the lower and upper values, respectively (i.e., $0.015 - 0.007 = 0.008$ BAC and $0.025 + 0.007 = 0.032$ BAC).

NHTSA proposes to use a Breath Alcohol Sample Simulator (BASS), non-alcoholic human breath, and a calibrating unit to test breath devices. The agency proposes to use preparations of bodily fluids or scientifically acceptable substitutes for non-breath devices. For example, the agency proposes to use aqueous alcohol test solutions equivalent to blood or saliva on a one-to-one basis to test saliva devices.

The agency proposes to conduct 40 trials under Test 1 (20 at .008 BAC and 20 at .032 BAC) and 20 trials under Test 2 (at .000 BAC). For reusable devices, these 60 trials would be conducted using a single unit. For disposable devices, these 60 trials would be conducted using 60 separate units.

Some alcohol screening devices indicate the presence of alcohol in a manner that is unambiguous and requires no interpretation, such as by the use of a light or numerical reading. For these devices, NHTSA proposes that Tests 1 and 2 (at .008, .032 and .000 BAC) would be performed by an investigator at the DOT Volpe National Transportation Systems Center (VNTSC). To conform with the Model Specifications, the device must perform with no positive results at .000 BAC, not more than one positive result at .008 BAC and not more than one non-positive result at .032 BAC. If the device is capable of providing a reading of greater than 0.000 BAC and less than 0.020 BAC, the device must perform with not more than one such result at .000 BAC.

Other devices indicate the presence of alcohol in a manner that requires interpretation and may involve some ambiguity, such as by the use of color changes. For these devices, NHTSA proposes that Tests 1 and 2 (at .008, .032 and .000 BAC) would be performed by ten individuals who have no knowledge of test BACs and qualify as test interpreters. VNTSC would select these individuals using manufacturer's restrictions, if any. These individuals would be asked to read the manufacturer's instructions for the interpretation of the device's read-out, and interpret the test results independently. To conform with the Model Specifications, the device must perform, with each interpreter, with no

positive results at .000 BAC, not more than one positive result at .008 BAC and not more than one non-positive result at .032 BAC. If the device is capable of providing a reading of greater than 0.000 BAC and less than 0.020 BAC, the device must perform, with each interpreter, with not more than one such result at .000 BAC.

Through the independent interpretation of ten individuals, NHTSA believes the Model Specifications would ensure that the results of tested devices are visible and will remain so for a reasonable period of time (the tests require approximately two hours to run), and are likely to be interpreted in a consistent manner. NHTSA requests comments on this aspect of the proposed Model Specifications.

To NHTSA's knowledge, no reusable devices use interpretive readings. Typically, these readings are produced using a chemical reaction, which results in a color change, a method which lends itself more readily to a single use device. For this reason, the agency believes it is unlikely that manufacturers would begin to use such interpretive readings in reusable devices. Accordingly, NHTSA has not proposed a methodology for testing reusable interpretive devices. We request comments on this aspect of the agency's proposal.

For disposable devices that use interpretive readings, the Model Specifications propose to combine Tests 1 and 2, and number the units and expose them to the three BAC levels using a methodology that would not reveal to the person interpreting the test the dosage received by any particular unit. NHTSA requests comments on this proposed methodology.

Devices would also be tested to determine whether acetone or, in the case of breath or saliva devices, cigarette smoke affects the functioning of the instruments. NHTSA requests comments on whether devices should be tested for interference from other substances. In addition, high (40°C) and low (10°C) ambient temperature and vibration tests would be conducted for these devices to determine their ability to function under a range of environmental conditions. NHTSA proposes that these tests (3.1, 3.2, 4.1, 4.2 and 5) would be performed by an investigator at VNTSC. Five trials would be conducted at .000 BAC under Test 3.2. Forty trials (including 20 at .008 and 20 at .032 BAC) would be conducted under each of these other tests.

To conform with the Model Specifications, the device must perform

¹ Jones, A.W., "Distribution of ethanol between saliva and blood in man," *Clinical and Experimental Pharmacology and Physiology*, 1979a, 6(1), 53-59.

Jones, A.W., "Inter- and intra-individual variations in the saliva/blood alcohol ratio during ethanol metabolism in man," *Clinical Chemistry*, 1979b, 25(8), 1394-1398.

Jones, A.W., "Quantitative relationships among ethanol concentrations in blood, breath, saliva and urine during ethanol metabolism in man," In Goldberg, L. (Ed.) *Alcohol Drugs and Traffic Safety*, Vol. II. Proceedings, 8th International Conference on Alcohol, Drugs and Traffic Safety, June 15-19, 1980, Stockholm, Sweden: Almqvist & Wiksell International, 1981, pp. 550-569.

with no positive results at each test performed at .000 BAC, not more than one positive result at each test performed at .008 BAC and not more than one non-positive result at each test performed at .032 BAC. If the device is capable of providing a reading of greater than 0.000 BAC and less than 0.020 BAC, the device must perform with not more than one such result at .000 BAC.

When devices such as these are used for medical purposes, the manufacturers of the devices are required to obtain marketing clearance from the Food and Drug Administration (FDA), in accordance with FDA regulations that address issues such as quality assurance in manufacturing, shelf-life and labeling. Currently, FDA does not assert jurisdiction (provide marketing clearance) for alcohol screening devices used for law enforcement purposes and workplace testing.

However, because of the nature of alcohol screening devices and the conditions under which they are to be used, NHTSA believes it is important for manufacturers of these devices to conform with certain requirements, imposed by FDA on devices used for medical purposes, prior to the inclusion of the devices on NHTSA's CPL.

Accordingly, NHTSA proposes to require that each device submitted for testing under the Model Specifications must be accompanied by a self-certification from the manufacturer, certifying that it meets the requirements contained in FDA's Good Manufacturing Practices regulations for devices used for medical purposes (21 CFR Part 820), and that the device's label meets the requirements contained in FDA's Labeling regulations for devices used for medical purposes (21 CFR Part 809.10), even if the devices are not to be used for medical purposes. By requiring a self-certification, NHTSA is not requiring that manufacturers obtain FDA marketing clearance, but simply that they self-certify that they believe that they have met the above-referenced requirements. (For technical assistance or a copy of the Device Good Manufacturing Practices Manual for Medical Devices, manufacturers should contact FDA's Division of Small Manufacturers by calling toll free at 1-800-638-2041.)

This notice includes, as an Appendix, a proposed set of Labeling Instructions for Alcohol Screening Devices that has been prepared in consultation with FDA to assist manufacturers of alcohol screening devices in developing a label that conforms to 21 CFR Part 809.10. The template addresses issues such as restrictions that may apply to operators of the device and conditions under

which the device should or should not be operated.

These Model Specifications are not regulations. Organizations and agencies may adopt these Model Specifications and rely on NHTSA's test results or may conduct their own tests according to their own procedures and specifications. It should be noted, however, that transportation employers covered by 49 CFR Part 40, Procedures for Transportation Workplace Drug and Alcohol Testing Programs, are required to use only alcohol testing devices that meet the criteria established by that regulation. See DOT's final rule published elsewhere in today's *Federal Register*.

Once the Model Specifications for Alcohol Screening Devices are finalized and a CPL of conforming devices is published, DOT will issue procedural rules for using approved alcohol screening devices in transportation workplaces, including provisions for how and where such devices could be used and the steps that must be taken to collect bodily fluids.

Procedures

NHTSA proposes that testing of products submitted by manufacturers to these Model Specifications would be conducted by the DOT Volpe National Transportation Systems Center (VNTSC), DTS 75, Kendall Square, Cambridge, MA 02142. Tests would be conducted semiannually, or as necessary. Manufacturers would be required to apply to NHTSA for a test date by writing to the Office of Alcohol and State Programs (OASP), NTS-21, NHTSA, 400 Seventh Street, SW., Washington, DC 20590. Normally, at least 30 days would be required from the date of notification until the test could be scheduled.

One week prior to the scheduled initiation of the test program, a manufacturer would be required to deliver its devices to VNTSC. If the devices are disposable, the manufacturer would be required to deliver 300 such devices; if the devices are reusable, the manufacturer would be required to submit only a single device. If a manufacturer wishes to submit a duplicate, backup instrument, however, it may do so. The manufacturer would be responsible for ensuring that the devices operate properly and are packaged correctly. The manufacturer would also be required to deliver the operator's manual (or instructions) and the maintenance manual (if any) supplied with the purchase of the device, as well as specifications and drawings which fully describe these devices. Proprietary information would

be respected. (See 49 CFR Part 512, regarding the procedure by which NHTSA will consider claims of confidentiality.)

In addition, the manufacturer would be required to submit a self-certification, certifying that the manufacturer meets the requirements in FDA's Good Manufacturing Practices regulations for devices used for medical purposes (21 CFR Part 820), and that the device's label meets the requirements in FDA's Labeling regulations for devices used for medical purposes (21 CFR 809.10) even if the devices are not to be used for medical purposes. See Appendix to this notice.

NHTSA proposes that the manufacturer would have the right to check its devices between the time of their arrival at VNTSC and the start of the tests, but would have no access to the devices during the tests. Any malfunction of a device which results in failure to complete any of the tests satisfactorily would result in a determination that the device does not conform to the Model Specifications. If a device is found not to conform, it may be resubmitted for the next testing series after appropriate corrections have been made.

Following publication of this notice and the public comment period, NHTSA plans to publish a second notice in the *Federal Register* containing the final Model Specifications. After the second notice is published, NHTSA plans to begin testing of alcohol screening devices to determine whether they comply with the performance criteria included in the Model Specifications.

A Conforming Products List (CPL) will be published and updated periodically. It will include a list of alcohol screening devices that were submitted with the proper certifications and found to meet or exceed the proposed Model Specifications.

NHTSA proposes to modify and improve these Model Specifications as new data and test procedures become available and to alter the test procedures, if necessary, to meet unique design features of a specific device. For each such modification, NHTSA would provide notification in the *Federal Register* and would retest devices when necessary.

OASP would be the point of contact for information about acceptance testing and field performance of devices. NHTSA requests that users of these devices provide both acceptance and field performance data to OASP when such data are available. Information from users would help NHTSA monitor whether alcohol screening devices are

performing according to the NHTSA Model Specifications.

If information gathered indicates that a device on the CPL is not performing in accordance with the Model Specifications, NHTSA would direct VNTSC to conduct a special investigation. An investigation may include visits to users and additional tests of the device obtained from the open market. If the investigation indicates that the devices actually sold on the market are not meeting the Model Specifications, the manufacturer would be notified that the device may be removed from the list. In this event, the manufacturer would have 30 days from the date of notification to reply. Based on the VNTSC investigation and any data provided by the manufacturer, NHTSA would decide whether the device should remain on the list. If the device is removed from the list, the manufacturer would be permitted to resubmit an improved device to VNTSC for testing when it believes the problems causing its failure have been resolved. Upon resubmission, the manufacturer would be required to submit a statement describing what has been done to overcome the problems which led to failure of the device.

If information gathered indicates that the manufacturer of a device on the CPL does not comply with the requirements in FDA's Good Manufacturing Practices regulations for devices used for medical purposes or that the device's label does not comply with the requirements in FDA's Labeling regulations for devices used for medical purposes, NHTSA would investigate the matter in consultation with FDA and would notify the manufacturer that the device may be removed from the list. The manufacturer would have 30 days from the date of notification to reply. Based on any data provided by the manufacturer and investigative findings, NHTSA would decide whether the device should remain on the list. If the device is removed from the list, the manufacturer would be permitted to resubmit a self-certification, certifying that the manufacturer complies with these FDA requirements when it believes the problems causing its non-compliance have been resolved. Upon resubmission, the manufacturer would be required to submit a statement describing what has been done to overcome the problems which led to non-compliance.

Comments

Interested persons are invited to comment on this proposal. Comments are sought on the proposed conversion factors included in these proposed

Model Specifications, particularly for saliva, and what may constitute acceptable criteria for bodily fluids other than saliva, blood and breath.

Related issues regarding screeners that are of interest include the potential of interfering substances (i.e. nicotine and acetone) to affect results, and whether the Model Specifications should test for additional potentially interfering substances.

NHTSA also requests comments, particularly from manufacturers or users (and potential users) of these devices, regarding problems that have occurred or could arise due to insufficient labeling or manufacturing practices. Commentors should identify issues they believe need to be addressed by NHTSA's notice regarding manufacturing practices and labeling requirements, and indicate whether they believe FDA regulations are most appropriate to address these issues. Alternatively, if commentors believe there is not a need to apply manufacturing practices and labeling requirements to alcohol screening devices when used for law enforcement and workplace testing purposes, they should submit comments to this effect and include the reasons for their belief.

It is requested but not required that 10 copies be submitted. Comments must not exceed 15 pages in length (49 CFR 553.221). Necessary attachments may be appended to those submissions without regard to the 15 page limit. This limitation is intended to encourage commentors to detail their primary arguments in a concise fashion.

All comments received before the close of business on the comment closing date indicated above will be considered, and will be available for examination in the docket at the above address, both before and after that date. To the extent possible, comments filed after the closing date will also be considered. However, the Model Specifications may be published at any time after that date, and any comments received after the closing date and too late for consideration with regard to the action will be treated as suggestions for future revisions to the specifications. NHTSA will continue to file relevant material in the docket after the closing date as it becomes available. It is recommended that interested persons continue to examine the docket for new material.

Those persons who desire to be notified upon receipt of their comments in the docket should enclose a self-addressed stamped postcard in the envelope with their comments. Upon receiving the comments, the docket

supervisor will return the postcard by mail.

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 and it has been determined that it has no federalism implication that warrants the preparation of a federalism assessment.

In accordance with the foregoing, the proposed Model Specifications for performance testing of alcohol screening devices are set forth below.

Authority: 23 U.S.C. 402; delegations of authority at 49 CFR 1.50 and 501.

Michael B. Brownlee,

Associate Administrator for Traffic Safety Programs.

Model Specifications for Alcohol Screening Devices

1. Purpose and Scope

These specifications establish performance criteria and methods for testing of alcohol screening devices. Alcohol screening devices use bodily fluids to detect the presence of 0.020 or more BAC with sufficient accuracy for screening purposes. These specifications are intended primarily for use in the conformance testing of alcohol screening devices.

2. Classification

2.1 Disposable Alcohol Screening Devices

Alcohol screening devices designed for a single use.

2.2 Reusable Alcohol Screening Devices

Alcohol screening devices designed to be reused.

3. Definitions.

3.1 Alcohol

The intoxicating agent in beverage alcohol, ethyl alcohol or other low molecular weight alcohols including methyl or isopropyl alcohol.

3.2 Alcohol Screening Device

A device that is used to detect the presence of 0.020 or more BAC. The device may measure any bodily fluid for this purpose, but shall provide output in BAC units. Test results may be indicated by numerical read-out or by other means, such as by the use of lights or color changes.

3.3 Blood alcohol concentration (BAC)

Grams alcohol per 100 milliliters of blood or grams alcohol per 210 liters of breath in accordance with the Uniform Vehicle Code, Section 11-903(a)(5)² (BrAC is often used to indicate that the

² Available from the National Committee on Traffic Laws and Ordinances, 405 Church Street, Evanston IL 60201.

measurement is a breath measurement); or grams alcohol per 100 milliliters of saliva.

3.4 Calibrating Unit

A device that produces an alcohol-in-air test sample of known concentration that meets the NHTSA Model Specifications for Calibrating Units (49 FR 48865).

3.5 Breath Alcohol Sample Simulator (BASS)

A device that provides an alcohol-in-air test sample with known and adjustable alcohol concentration profile, flow rate, and air composition at 34° centigrade. (See NBS Special Publication 480-41, July 1981³ for a description of a BASS unit suitable for use in the required testing.)

3.6 Bodily Fluid

Any bodily fluid capable of being used to estimate alcohol concentration, provided the relationship between such bodily fluid and BAC has been established according to scientifically acceptable standards. Such fluids include but are not limited to blood, exhaled deep lung breath and saliva.

3.7 Scientifically Acceptable Substitutes

Fluids that have been scientifically accepted as equivalent to bodily fluids for testing purposes, such as aqueous alcohol test solutions on a one-to-one basis for blood or saliva.

4. Test Methods and Requirements

Testing will be performed according to the instructions which normally accompany the submitted device and under the conditions specified in the tests below.

4.1 Test 1. Precision and Accuracy.

Perform 40 trials under normal laboratory conditions, including 20 trials at 0.008 BAC and 20 trials at 0.032 BAC. Use the BASS device for breath devices and preparations of bodily fluids or scientifically acceptable substitutes for non-breath devices.

For disposable alcohol screening devices that indicate the presence of alcohol in a manner that requires interpretation, combine Tests 1 and 2, in accordance with 4.3 below.

For alcohol screening devices that indicate the presence of alcohol in a manner that does not require interpretation, perform the test using a VNTSC investigator. To conform at 0.008 BAC, not more than one positive result. To conform at 0.032 BAC, not more than one non-positive result.

4.2 Test 2. Blank Reading.

Perform 20 trials under normal laboratory conditions at 0.000 BAC. Use non-alcoholic human breath for breath devices and preparations of non-alcoholic bodily fluids or scientifically acceptable substitutes for non-breath devices.

For disposable alcohol screening devices that indicate the presence of alcohol in a manner that requires interpretation, combine Tests 1 and 2, in accordance with 4.3 below.

For alcohol screening devices that indicate the presence of alcohol in a manner that does not require interpretation, perform the test using a VNTSC investigator. To conform, no positive results. If the device is capable of providing a reading of greater than 0.000 BAC and less than 0.020 BAC, not more than one such result.

4.3 Methodology for Combining Tests 1 and 2 for Disposable Interpretive Devices.

Perform the test using ten individuals who qualify as test interpreters (according to the manufacturer's restrictions, if any) and who have no knowledge of test BACs. Ask each individual to read the manufacturer's instructions for interpretation of the device's read-out.

Label sixty devices from 1 to 60 and randomly separate them into three groups of twenty. Record the numbers in each group. Use two of the groups of devices for Test 1 and the remaining group for Test 2. Dose each group at the BAC levels specified in Tests 1 and 2. Order the sixty devices into a single set from 1 to 60 and ask each individual to independently interpret the results of these trials.

Ask each individual to record each result as being one of the following: "at .00 BAC"; "above .00 and below .02 BAC"; "at or above .02 BAC"; or "can't tell". Dosing of devices and interpretation of results will be accomplished within a two hour period.

To conform, with each interpreter, no positive results at .000 BAC, not more than one positive result at .008 BAC and not more than one non-positive result at .032 BAC. If the device is capable of providing a reading of greater than 0.000 BAC and less than 0.020 BAC, with each interpreter, not more than one such result at .000 BAC.

4.4 Interference

Test for the effect of acetone and, in the case of breath or saliva devices, cigarette smoke.

4.4.1 Test 3.1. Acetone.

Perform 40 trials, including 20 trials at 0.008 BAC and 20 trials at 0.032 BAC. Use a calibrating unit for this test for breath devices and preparations of

bodily fluids or scientifically acceptable substitutes for non-breath devices.

Prepare test BACs to include an acetone concentration equivalent to a BAC of 0.010 grams per 100 milliliters blood. For breath screening devices, add 115 microliters of acetone per 500 milliliters of solution for use in the calibrating unit.⁴

To conform at 0.008 BAC, not more than one positive result. To conform at 0.032 BAC, not more than one non-positive result.

4.4.2 Test 3.2. Cigarette smoke (breath and saliva test devices only).

Perform five trials at 0.000 BAC. Use non-alcoholic human breath for breath devices and preparations of non-alcoholic bodily fluids or scientifically acceptable substitutes for non-breath devices.

Select a person who smokes cigarettes for this test. Ask the person selected to smoke approximately one half of a cigarette. Within one minute after smoking, or after a waiting period specified in the manufacturer's instructions, ask him or her to blow into the screening device according to manufacturer's instructions. Then ask the person to smoke another inhalation and repeat the test to produce a total of five trials.

To conform, no positive results.

4.5 Temperature.

Test at low and high ambient temperature.

4.5.1 Test 4.1 Low Ambient Temperature.

Perform 40 trials at 10°C, including 20 trials at 0.008 BAC and 20 trials at 0.032 BAC. Use a calibrating unit for this test for breath devices and preparations of bodily fluids or scientifically acceptable substitutes for non-breath devices.

To conform at 0.008 BAC, not more than one positive result. To conform at 0.032 BAC, not more than one non-positive result.

4.5.2 Test 4.2 High Ambient Temperature.

Perform trials of 40 devices at 40°C, including 20 trials at 0.008 BAC and 20 trials at 0.032 BAC. Use a calibrating unit for this test for breath devices and preparations of bodily fluids or scientifically acceptable substitutes for non-breath devices.

To conform at 0.008 BAC, not more than one positive result. To conform at 0.032 BAC, not more than one non-positive result.

4.6 Test 5.0. Vibration.

Perform 40 trials, including 20 trials at 0.008 BAC and 20 trials at 0.032 BAC.

⁴Based on an experimentally determined water to air partition factor 365 to 1 at 34° to yield acetone-in-air concentrations of 0.5 milligrams per liter.

³Available from Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Use a calibrating unit for this test for breath devices and preparations of bodily fluids or scientifically acceptable substitutes for non-breath devices.

Mount the screening device on a shake table and vibrate the table in simple harmonic motion through each of its three major axes, as specified below. Sweep through each frequency range in 2.5 minutes, then reverse the sweep to the starting frequency in 2.5 minutes. The 40 disposable testers may be placed in a suitable box mounted on the shake table. Test after vibration.

Frequency (hertz)	Amplitude (inches, peak to peak)
10 to 30	0.30
30 to 60	0.15

To conform at 0.008 BAC, not more than one positive result. To conform at 0.032 BAC, not more than one non-positive result.

Appendix—Labeling Instructions for Alcohol Screening Devices

Intended Use

Provide the intended use including the specimen matrix (e.g. saliva, breath), the assay type (quantitative, semi-quantitative) the purpose of performing the assay and the individual designated to perform the assay.

e.g. This product is intended for the (quantitative, semiquantitative) determination of alcohol in—define matrix (for e.g., saliva, breath, sweat) to perform screening alcohol assays. This product is recommended for use by individuals who have been trained in the administration of screening devices.

Description of Testing System

Provide the principles of the procedure for performing the alcohol screening assay.

e.g. This product uses alcohol dehydrogenase, infrared technology, etc. to perform the test.

Chemical Reaction Sequence

Describe the chemical reaction sequence, if applicable.

Reagents

List the concentration, strength, composition of the reactive ingredients. List the non-reactive ingredients.

Reagent Preparation and Storage

Provide instructions for preparing the reagents, if applicable.

Provide the instructions for storing the reagents, if applicable.

Provide any signs of deterioration of the reagents, if applicable.

Provide the reagent's shelf life and opened expiration dating, if applicable.

e.g. Unopened tests are stable until the date printed on the product container when stored at 22–28°C. Opened test must be used at once.

Provide a caution not to use the reagents beyond the expiration dating.

Precautions

1. List any reagents that may be hazardous such as caustic compounds, sodium azide or other hazardous reagents and instructions for disposal, if applicable.

2. If visually read, warn the user the result should not be interpreted by readers who are color-blind or visually impaired.

3. Provide warning to user to treat all samples as potentially infective. Include instructions for handling and disposal of the sample.

Specimen Collection

Provide instructions for collecting and handling the sample.

Provide criteria for specimen rejection, if applicable.

Calibration

Disposable tests are pre-calibrated. No additional calibration is required.

Reusable (Instrumented) tests require calibration.

Provide information regarding how calibrations are to be conducted, if applicable, including the number and concentration of calibrators, and the frequency of calibration.

Provide instructions for calibration and recalibration.

Provide the criteria for acceptability of calibration.

Test Procedure (Disposable)

Provide adequate step-by-step instructions for performing the test.

If the test is disposable (non-instrumented) and involves a color reaction, include the time frame for

which the test must be read and recorded.

e.g. Read within 15 minutes.

Test Procedure (Reusable/Instrumented)

Provide adequate step-by-step instruction for performing the test.

Provide the installation procedures and, if applicable, any special requirements.

Provide the space and ventilation requirements.

Provide the description of the required frequency of equipment maintenance and function checks.

Provide the instructions for any remedial action to be taken when the equipment performs outside of operating range.

Provide any operational precautions and limitations.

Provide the instructions for the protection of equipment and instrumentation from fluctuations or interruptions in electrical current that could adversely affect test results and reports, if applicable.

Quality Control (QC)

Disposable Tests

If applicable, the function and stability of the test can be determined by examination of the procedural "built in" controls contained in the product. If these controls are not working, the test is invalid and must be repeated.

Disposable/Instrumented Devices

If external quality control materials are used, provide number, type, matrix and concentration of the QC materials.

Provide directions for performing quality control procedures. Provide an adequate description of the remedial action to be taken when the QC results fail to meet the criteria for acceptability.

Provide directions for interpretation of the results of quality control samples.

Results

Describe how the user obtains the test results, from a colored bar, instrument read-out, printout, etc.

Describe the results in terms of blood alcohol concentration.

Describe what concentration indicates a positive result and what concentration indicates a negative result.

Limitations

List the substances or factors that may interfere with the test and cause false results including technical or procedural errors.

Dynamic Range

Provide the operating range of the product.

Precision and Accuracy

Precision and Accuracy specifications are included in the National Highway

Traffic Safety Administration's (NHTSA's) Model Specifications for Alcohol Screening Devices. Only devices that meet these model specifications will be included on NHTSA's Conforming Products List for alcohol screening devices.

Specificity

List the substances that have been evaluated with your product that do or do not interfere at the concentration indicated.

References

Provide pertinent bibliography

Technical Assistance

List an 800 number the user may contact for further information or technical assistance.

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